Technical Guidance for HIV/AIDS Surveillance Programs

Electronic Reporting

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Contents — Electronic Reporting

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Introduction

Purpose of Electronic Reporting

With the growing sophistication of information technology, surveillance data can now be transmitted, stored, manipulated, and analyzed electronically in a secure environment. These advancements are changing the way HIV/AIDS surveillance activities are conducted and what can be achieved. Electronic reporting of data for both cases and lab results should enhance current surveillance practices, as long as technical capability is in place to integrate electronic reporting into routine surveillance practices. As manual entry or re-entry of data diminishes, the efficiency of surveillance activities should also improve. Information can be transmitted to and received by HIV/AIDS surveillance programs in a timelier manner. When case confirmatory lab results and case data from confluent data streams are linked and complementary data combined, a number of beneficial effects follow: case ascertainment should be enhanced; surveillance data received passively should be more complete; progression of disease in cases should be identified; and unmet health care need should be easier to ascertain. Accuracy of data should also improve as errors that used to occur when entering case information or lab results from paper copies will now be limited to the initial point of data entry, and conflicting information from various data sources can be identified and reconciled. As less paper is used, storage and security of confidential reports will also be improved.

Electronic Case Reporting (ECR)

Definition: An HIV/AIDS case report that arrives in a pre-established electronic format (e.g., HL7 data stream, ASCII, spreadsheet) and does not require extensive human intervention (e.g., data entry, cutting and pasting, or translation) to add it to a database.

Electronic case reporting, ECR, is used by <10% of HIV/AIDS reporting areas (1). The emphasis on electronic laboratory reporting, coupled with lack of resources, has forced a number of areas to lower their prioritization for implementation of ECR. Nevertheless, in the Electronic Case Reporting (ECR) section of this chapter, steps that have been used by those conducting ECR are included as a guide for those areas considering implementing ECR. As an integrated nationally notifiable electronic disease surveillance system is established, states may be able to build upon a communicable disease reporting infrastructure for ECR.

The use of electronic case reports from reliable sources can help identify new cases and facilitate reporting of existing cases, complete case report information of HIV disease, and improve the accuracy and completeness of patient identifiers and demographic and risk

information. With careful planning and proper implementation, ECR can also redistribute some portion of staff time currently dedicated toward medical record abstraction and data entry for HIV/AIDS surveillance.

Electronic Laboratory Reporting (ELR)

Definition: Laboratory reporting that arrives in a pre-established electronic format (e.g., HL7 data stream, ASCII, spreadsheet) and does not require extensive human intervention (e.g., data entry, cutting and pasting, or translation) to add it to a database.

Electronic laboratory reporting, or ELR (also known as electronic laboratory-based reporting), will markedly enhance passive identification of cases and enrich surveillance data from diagnosis to death. While most areas currently receiving ELR are receiving inadequate demographic surveillance information to complete a case report, thus requiring case follow-up, efforts are underway to encourage laboratories to submit this needed demographic information to public health departments, especially for newly diagnosed persons.

"ELR is an important component of CDC's public health information and surveillance systems integration efforts [that must be coordinated] with related efforts at CDC and in state and local public health agencies."

Electronic Reporting of Laboratory Information for Public Health
Centers for Disease Control and Prevention, Atlanta, GA
January 7-8, 1999

Lab data for HIV/AIDS surveillance can be used to

- find cases
- monitor care and treatment
- identify disease stage at diagnosis and progression to AIDS
- audit laboratories
- measure unmet health care need

Passive case reporting depends on a motivated reporting source and rarely results in complete case ascertainment. Active case finding at hospitals or specialty clinics is very resource-intensive but has been the most reliable method to identify cases, supplement case ascertainment, and collect complete surveillance case information. A great benefit of ELR will be to help speed the identification of new cases and provide a method for more complete case ascertainment when laboratories report diagnostic or other HIV testing results directly to state or local HIV/AIDS surveillance programs. These test results will be sent to surveillance programs at approximately the same time as to providers. As such, based on the type of lab test, the priority and method for follow-up will differ. Following a confirmatory HIV test result, surveillance programs will probably continue to conduct

follow-up to obtain complete case information from a provider; but other HIV-associated testing, such as CD4+ T-lymphocyte (CD4) counts, may need to be reserved until case identification has occurred. One potentially efficient way to ensure that CD4 count results are collected and reported at the time of HIV diagnosis is to use the opportunity for medical record abstraction from provider's offices. At that time, case information can be completed for *all* HIV-infected persons who are cared for by that provider, including initial CD4 count. Follow-up of additional CD4 results may, however, be delayed depending on the number and level of CD4 results that are reported and the available resources for follow-up.

The presence of lab testing for a newly diagnosed HIV-infected person can be a marker of access to health care, reflecting the successful linkage between diagnosis and entry into care. Furthermore, the timing and frequency of lab testing is a marker for meeting HIV treatment objectives and providing optimum quality of care. Decreasing CD4 counts and increasing viral load reflect the progression of HIV disease. Population-based CD4 counts at the time of initial HIV diagnosis provide a cross-sectional view of immune suppression and stage of disease among newly diagnosed HIV-infected persons. CD4 count at the time of diagnosis is an indicator of how well education, risk recognition, testing, and access to care are working. If early testing and detection for HIV is occurring, CD4 counts should be normal or near normal. Severely deficient initial CD4 counts, obtained at initial HIV diagnosis, that meet the current AIDS immunologic criteria, reflect a significant delay and missed opportunity for early treatment and prevention.

ELR can also be used to enhance completeness of surveillance activities. The volume of lab results received from a laboratory during a specified period of time establishes a baseline rate; this rate can be compared with that of lab reports received in the future to monitor for any discrepancies in laboratory reporting.

Twenty-eight (46%) of 61 HIV/AIDS surveillance areas reported in a 2004 survey that they received lab data electronically (data that arrived in a pre-established electronic format—e.g., HL7 data stream, ASCII, spreadsheet—and did not require extensive human intervention such as data entry, cutting and pasting, or translation to add it to a database). Of those, only two areas reported they have a state law/regulation/code that requires laboratories to report electronically, but neither specified a volume of testing for which reporting was mandated. Among the 33 surveillance areas not currently conducting ELR, 52% expected to begin ELR within the next 12 months. Lack of financial resources and lack of dedicated informatics personnel were the most frequently cited reasons among areas not planning on beginning ELR anytime soon.(1)

The Electronic Laboratory Reporting (ELR) section of this chapter outlines steps that should be considered when implementing electronic laboratory reporting.

Considerations for Electronic Reporting

Electronic reporting will necessitate some planning and implementation of safeguards by the HIV/AIDS surveillance program. Structural requirements for supporting electronic reporting are included in the section on Existing ELR Resources for Implementing HIV/AIDS Reporting. Practices and standards are also covered in detail in the Introduction to Policies and Procedures and Record Linkage chapters, and in Vol. III: Security and Confidentiality Guidelines.

Policy

Before implementing electronic reporting, HIV/AIDS surveillance programs should review existing state laws regarding requirements for communicable disease reporting, electronic reporting, and specifically HIV/AIDS reporting. Health Insurance Portability and Accountability Act (HIPAA) policies are covered in Vol. III: Security and Confidentiality Guidelines.

Security and Confidentiality

Security and confidentiality are covered in detail in Vol. III: Security and Confidentiality Guidelines. There are five guiding principles upon which all HIV/AIDS surveillance program requirements and security considerations are derived. They are

Guiding Principle 1 HIV/AIDS surveillance information and data will be maintained in a physically secure environment. Refer to sections Physical Security and Removable and External Storage Devices.

Guiding Principle 2 Electronic HIV/AIDS surveillance data will be held in a technically secure environment, with the number of data repositories and individuals permitted access kept to a minimum. Operational security procedures will be implemented and documented to minimize the number of staff that have access to personal identifiers and to minimize the number of locations where personal identifiers are stored. Refer to sections Policies, Training, Data Security, Access Control, Laptops and Portable Devices, and Removable and External Storage Devices.

Guiding Principle 3 Individual surveillance staff members and persons authorized to access case-specific information will be responsible for protecting confidential HIV/AIDS surveillance information and data. Refer to sections Responsibilities, Training, and Removable and External Storage Devices.

Guiding Principle 4 Security breaches of HIV/AIDS surveillance information or data will be investigated thoroughly, and sanctions imposed as appropriate. Refer to section Security Breaches.

Guiding Principle 5 Security practices and written policies will be continuously reviewed, assessed, and as necessary, changed to improve the protection of confidential HIV/AIDS surveillance information and data. Refer to sections Policies and Security and Confidentiality Program Requirement Checklist.

Note: See Vol. III: Security and Confidentiality Guidelines for each of the sections specified above.

Record Linkage

Linkage of new electronic lab records and case reports to an HIV/AIDS case can fulfill many purposes for surveillance: find cases, update patient status (e.g., verify the living status of a patient, monitor disease progression from HIV to AIDS to death, etc.), assess access to care, verify accuracy of information (e.g., race, state of residence, etc.), complete surveillance information (e.g., risk factors, presence of co-morbid conditions, etc.), and facilitate care and treatment services. Surveillance programs use this information to more accurately describe the epidemic, characterize epidemiologic changes, and assess effectiveness of intervention programs.

Processing large volumes of electronic case reports or electronic lab reports requires linkage with existing case surveillance records to determine whether the report should be linked to an existing case or whether a new case record should be created. Strategies for linkage to case reports can be found in the Record Linkage chapter.

Existing ELR Resources for Implementing HIV/AIDS Reporting

Background

Over the past several years clinical laboratories, hospitals, and government have recognized the need to develop standard ways of communicating electronic data. More recently a number of standards have evolved, and an increasing number of partners have adopted them.

The Department of Health and Human Services has identified three standards relevant to the content and format of transferring electronic laboratory data for the purposes of public health reporting. These include HL7 (Health Level 7), LOINC (Logical Observation Identifiers Names and Codes), and SNOMED (Systematized Nomenclature of Medicine), which are each described further below and in Appendix 1, Electronic Laboratory Reporting Resources. Any public health jurisdiction that is considering implementing an electronic laboratory reporting (ELR) system for HIV infection data should first identify whether other public health staff have already developed systems for transferring non-HIV data. In most cases the same systems can be employed, whether or not the data are contained within the same messages.

CDC has supported two major initiatives related to ELR. First proposed in 1999, the National Electronic Disease Surveillance System (NEDSS) incorporated a standards-based architecture that included processing electronic laboratory data. In 2003, NEDSS

became a component of the broader Public Health Information Network (PHIN) initiative. Both initiatives have brought together experts in a wide variety of fields to further develop and adopt these standards. Two Web sites, http://www.cdc.gov/nedss/ and http://www.cdc.gov/phin/, contain numerous resources necessary for implementing ELR.

NEDSS (National Electronic Disease Surveillance System)

ELR is an important component of NEDSS. The general goals are to

- detect outbreaks rapidly and provide national health data
- facilitate electronic transfer of data from clinical to public health settings
- reduce the burden of public health reporting
- enhance timeliness and quality of data

The NEDSS Base System is being developed for health departments to use and modify for surveillance and analysis of notifiable disease information. The base system elements include

- browser-based data entry and data management
- processing of electronic lab, clinical, and public health data in HL7 format
- an integrated data repository
- active data translation and exchange (integration broker) functionality
- use of contemporary application programming practices—component based, object oriented, and cross platform where possible
- data reporting and visualization capability
- a shareable directory of public health personnel
- a security system and appropriate security policies

PHIN (Public Health Information Network)

The NEDSS Base System and ELR are important components of PHIN. Its broader vision includes

- automated data exchange
- use of electronic clinical data for event detection
- manual data entry for event detection
- specimen and lab result information management and exchange
- management of case, contact, and threat data
- analysis and visualization
- directories of personnel
- public health information and alerting
- information technology (IT) security and critical infrastructure protection

ELR Requirements

For the system to work across the full range of partners, all transactions must be standards-based. Some of the standards that must be in place regardless of the content and format of data transfers include the security and messaging standards. These are well beyond the scope of this document, but information on secure file transfer methods, the PHIN messaging system, XML (eXtensible Markup Language), and other terminology is available at the PHIN Web site. The standards that *are* specific to ELR are HL7, SNOMED, and LOINC.

HL7 (Health Level 7)

Health Level 7 provides interoperability between health care information systems by specifying standards for the exchange, management, and integration of data that support clinical patient care and the management, delivery, and evaluation of health care services. More information about this American National Standards Institute-accredited standard is available at www.hl7.org.

HL7 defines the structure and syntax of an electronic message, so the sender knows where to place information and the receiver knows where to find it. Each defined segment contains several fields. Common segments for electronic laboratory reporting include the Patient Identifier, Next of Kin, Common Order (ordering facility and provider), Observation Request (requested tests), and Observation Result (the lab results).

Note: HL7 allows coding of the laboratory tests and results using SNOMED or LOINC.

SNOMED (Systematized Nomenclature of Medicine)

The College of American Pathologists has been developing this system since 1965. SNOMED CT is a dictionary of clinical terms that includes every clinically relevant organism that might be identified by a laboratory.

LOINC (Logical Observation Identifiers Names and Codes)

The Regenstrief Institute developed this dictionary of lab tests and results.

Note: See Appendix 1 for additional information about general ELR in ELR Resources.

Electronic Case Reporting

Electronic case reporting, as of June 2004, was being conducted by a small number of HIV/AIDS reporting areas[1], and most are in the early stages of implementation. Of the 55 sites that were not currently receiving case reports electronically, eight were planning to begin electronic case reporting within the next 12 months (1).

Because so few areas have begun implementing electronic case reporting, it is recommended that the steps listed below be implemented in stages—beginning with providers that report the largest number of cases—with the goal that all providers will eventually report all cases electronically. The growing use of electronic medical records may make electronic case reporting less burdensome for facilities and providers. Nevertheless, the need to conduct field follow-up of potential new cases will not be completely eliminated with electronic case reporting.

Review Reporting Laws

Review your state laws and work toward making additions or modification as needed. Consider these examples:

- If possible, implement mandatory electronic reporting of HIV/AIDS case data from facilities and providers, specifying the timeframe in which the HIV/AIDS surveillance program should receive the report. If this is not possible, the surveillance program should strongly encourage and facilitate voluntary reporting.
- Identify which specific case fields are required to be reported.
- Include provisions for dealing with facilities and providers within and outside of the state's boundaries.
- Clarify policies for out-of-state case reporting that occurs via paper or electronically.

Erroneous interpretations of HIPAA can be a serious hindrance to establishing case reporting. The state's reporting regulations should acknowledge the provisions in HIPAA that deal with public health reporting. HIPAA permits reporting requirements established under state law. Therefore, the methods and procedures mandated by state laws or regulations are not prohibited by HIPAA. (HIPAA policies are covered in Vol. III: Security and Confidentiality Guidelines.

1. Los Angeles, NC, PA, PR, San Francisco

Develop a System for Reporting

- Determine if your program can use or adapt an existing secure electronic system in your health department. In some instances, there may be a way to integrate HIV/AIDS surveillance data into an existing or planned state system.
- If your state does not have an existing secure electronic system, a universally available method, such as a database, that stores case information in a uniform, standard format should be available to all HIV/AIDS surveillance sites.
- eHARS or NEDSS should provide a platform for collecting case information securely and confidentially.

Identify All Reporting Facilities and Providers

Identify all facilities and providers that need to report to your program, using local HIV/AIDS surveillance data and other available data sources, and identify a contact person at each facility/provider; establish a relationship with this person. Simply knowing who to call saves time. Educating contact persons so that they have a clear understanding of reporting requirements and mechanisms promotes prompt, accurate, and complete reporting from providers of surveillance data.

- Explore programs at other agencies—explore other programs such as the Ryan White Comprehensive AIDS Resources Emergency Act administered by the Health Resources and Services Administration (HRSA) or the Medicaid program, which may maintain a list of providers that they use for administrative and/or reimbursement purposes.
- Consult with other HIV/AIDS surveillance activities—consider special, new, or existing projects—to identify reporting providers and established relationships. Activities to consider include HIV Incidence and Viral Resistance Surveillance and the Morbidity Monitoring Project.
- Have your facility and provider list reviewed by field surveillance staff for completeness and accuracy.
- Contact each large reporting provider, establish a relationship with someone who has a good overview of the entire operation, and ask that person to complete a survey of how many new HIV/AIDS cases the facility has annually.
- Identify those provider facilities that are ready and willing to participate in electronic case reporting and have the capacity to generate and submit electronic files.

Documentation for Reporting Facilities and Providers

Develop and disseminate reporting documentation for your state that includes data structure and layout.

- Provide facilities and providers with a list of reportable diseases/conditions reflecting your state reporting regulations. In some instances, reference to the actual regulations may also need to be provided.

- Provide facilities and providers with a list of fields that must be completed to report a case electronically. (Some common fields are probably recorded for use with electronic patient medical records. Means by which these data fields can be exported for electronic case reporting should be explored.)
  - ASCII or area-specific alternative format should be accepted.
  - Paper reports should continue to be accepted.
- Resolve confidentiality and data transfer/security issues with each provider facility depending upon its IT capability. Adherence to CDC as well as HIPAA standards for confidentiality and secure data transfer will be required.
- Establish a reporting schedule that meets the needs of both the surveillance program and local laws and regulations.
- Consider holding training session(s) for facility staff as a mechanism for explaining reporting details.
  - Because of the clinical- and surveillance-specific nature of many of the data fields required for reporting, it may be necessary to work closely with and educate facility or provider staff unfamiliar with surveillance. For example, the type of information necessary to complete risk factor fields may not be appreciated or understood by provider staff responsible for "abstracting" information into an electronic case report. This is especially true if IT staff are storing and extracting information from data warehouses or electronic medical records for surveillance purposes.
- Use CDC's paper case report form as the template for the electronic case report form.
- Develop a user-friendly software to facilitate electronic reporting.

Note: See Appendix 2 for examples of variable lists for electronic case reporting. Two historical examples—(A) and (B) of Documentation for Reporting Facilities and Providers—have been provided.

Alternative Reporting Methods

Offer alternative methods of reporting if provider facility cannot report electronically or cannot adapt to using your particular system.

- Be aware that facilities have limits in their own systems.
- Resolve confidentiality and data transfer/security issues with each provider facility depending upon its IT capability.
- Consider an HIV/AIDS-specific electronic method that small facilities or providers could use. Web-based, secure reporting to enter facility or provider data may be needed.

Data Processing of Electronic Case Reports

- All electronic provider data of disparate formats will need to be converted to a standardized format that is compatible with HARS or eHARS. All reported cases should be linked with the registry to determine if the same person has been previously reported. (See Record Linkage.)
- Linked case reports can be used to update HARS records in the following order:
  1) cases reclassified from HIV to AIDS
  2) risk factor information changed from undetermined to one of the valid risk factor groups
  3) cases whose date of HIV/AIDS diagnosis changed to an earlier year
  4) other types of updates that will enhance the quality of the data
- Nonlinked cases may represent new case reporting. These new case reports and the linked ones that will reclassify the case from HIV to AIDS should be validated. When working with a large volume of reports, select a random sample for a validation project. This can help identify recurring problems from reporting sites.
- To evaluate the quality of the information extrapolated from electronic medical records, sample electronic case reports that link with manually reported HARS records and compare with the information obtained from manual reporting.
- New case reports with high-quality, complete data may be uploaded to the surveillance database followed by routine data re-abstraction. (See Data Quality.)

Reporting Back to Reporting Facilities and Providers

Develop a procedure for reporting back to provider facilities or local area public health departments responsible for case follow-up on incomplete reports. Consider use of an "audit," a "quality control," or a "report card" as a formal means to report back.

- Provide local area public health departments with periodic, ongoing case report summaries or case line lists to ensure consistency in case counts and quality of aggregate data.
- Supply feedback to providers with the evaluation results. Systematic errors that are caused by programming should be resolved before accepting the first batch of cases. A good practice is to inform the provider of errors such as incorrect death date, diagnosis, and birth date to improve the consistency between provider data and HARS.

Electronic Laboratory Reporting

Electronic laboratory reporting (ELR), also referred to as electronic laboratory-based reporting, provides an opportunity for HIV/AIDS surveillance programs to enhance their ability to conduct timely and complete surveillance. Drawing on experience from sites using ELR, this section outlines steps surveillance areas should contemplate for initiating ELR.

A number of structural requirements are necessary for ELR. They include

- hardware to support ELR functions
- software that allows importing, linking, and retention of electronic reports
- trained personnel to manage ELR and ELR-related activities

In addition to this guide for getting started, areas lacking ELR experience should consult with and take advantage of the experience and knowledge from those already conducting ELR. Additionally, 28 areas[2] reported in 2004 that they were receiving laboratory data electronically (1).

Review Reporting Laws

Laboratory test results, in accordance with state reporting laws, can be categorized as one of two types: *required* or *optional reports*. Those HIV and HIV-associated test results that are legislatively mandated to be reported to surveillance programs are required reports; those HIV and HIV-associated tests results for which reporting is not mandatory but may be sent voluntarily to surveillance programs are optional reports.

A first step toward implementing ELR is to review your state laws and work toward making additions or modifications as needed. Consider these examples:

- If possible, make reporting of HIV and HIV-associated test results from laboratories mandatory, specifying timeframe in which the HIV/AIDS surveillance program should receive these required reports.
- If possible, make *electronic* reporting of HIV data from laboratories mandatory, specifying timeframe in which the HIV/AIDS surveillance program should receive these required reports.
- Identify specifically what test results are to be reported along with specimen identification code (i.e., accession number) and either a LOINC code or local code.
- Identify specifically what types of patient demographic data are reportable.
- Specify what type of information is required to identify the laboratory and provider, i.e., Clinical Laboratory Improvement Amendments (CLIA) number, name and address of laboratory, name and phone number of laboratory contact, name and address of facility that specimen originates from, and name of physician ordering test.
- Specify how to handle data that are from an intermediate or a pass-through laboratory. If the laboratory performing the test cannot provide the name and address of the true provider, it must provide contact information for the intermediate laboratory as well as the accession number of the test so that it is possible to work back to the point where the patient and the true provider can be identified.

2. AZ, CO, HI, Houston, IL, IN, KS, KY, Los Angeles, LA, MD, MN, MS, MT, NJ, NY, NC, OH, OK, PA, PR, San Francisco, SC, TX, UT, WA, WI, WY

- Specify provisions for dealing with laboratories within and outside of the state's boundaries.
- Clarify policies for out-of-state case reporting that occurs via paper or electronically.

Three-quarters of reporting areas surveyed indicated they communicate lab report information received for nonresident individuals to the individual's home state HIV/AIDS program. One area indicated that state regulations prohibit forwarding lab results. (1)

  - Areas have developed various methods of handling out-of-state reporting, depending on their reporting regulations and resources. Three examples are
    - Reports are simply forwarded to the appropriate state.
    - Lab reports identifying new cases are entered into the local HIV/AIDS surveillance database but attributed to the appropriate state.
    - Lab reports are entered into a separate database and communicated to the appropriate state.
  - Areas must also develop policies for receiving ongoing lab reports on individuals with a current residence locally but with an HIV or AIDS diagnosis in another state.
- In some cases it is valuable to have the clear authority to collect HIV-negative test results, such as for seroreverting perinatal exposures or undetectable viral loads. Many laboratories will only report positive test results, however.
- Extra planning in developing reporting laws can save a lot of time and frustration in the long run. Making assumptions that certain items will be negotiable or that they are implied in existing regulations can become very problematic. Large hospital and private laboratories may wish to conduct an internal legal review of the state's reporting regulations before implementing new reporting procedures. Also, each HIV program should consult its public health laboratory for assistance in writing laboratory reporting regulations that use appropriate language for securing reporting from a wide range of laboratories.
- Erroneous interpretations of HIPAA can be a serious hindrance to establishing laboratory reporting. The state's reporting regulations should acknowledge the provisions in HIPAA that deal with public health reporting. HIPAA permits disease reporting requirements established under state law. (HIPAA policies are covered in Vol. III: Security and Confidentiality Guidelines and in a 2003 CDC *MMWR* publication available at http://www.cdc.gov/mmwr/PDF/wk/mm52SU01.pdf.)
- Hospital laboratories may try to defer reporting to Infection Control. The reporting regulations should clearly state that all laboratories must additionally report to Infection Control.

Develop a Mechanism for Electronic Reporting

Determine if your health department has an existing secure system for electronic reporting that your program can use or adapt. In some instances, there may be a way to integrate ELR for HIV/AIDS surveillance into an existing or a planned state system. If your state does not have an existing system that can be used, your program will need to consider the resources necessary for designing and developing your own secure system for laboratories to use to transmit data. Some options to consider are to

- hire consultants
- borrow internal resources
- hire systems persons or developers/programmers
- research the possibility of using third party products—some laboratories may already be familiar with some of these

While implementing electronic reporting, the surveillance program may need to reorganize human resources by recruiting more staff with skills to process data, such as SAS programmers, or sending existing staff for training on data management and data analysis.

Identify All Reporting Laboratories

Identify laboratories that are conducting tests required to be reported, such as Western blot, CD4, and viral load tests. Identify a specific contact person at each laboratory and establish an ongoing relationship with this person.

Of 32 reporting areas not conducting electronic laboratory reporting, over 90% have identified which laboratories report which test results to them. Over 60% have begun discussions with their laboratories about reporting electronically to their program. (1)

To compile a list of laboratories needing to report, beginning with an inventory of laboratories in HARS, consider these available sources:

- Start by approaching the state agency responsible for conducting laboratory proficiency testing. For most states, with the exception of Washington and New York, the agency will be CMS (Centers for Medicare and Medicaid Services)-CLIA (Clinical Laboratory Improvement Amendments). CMS-CLIA regional offices can provide the same information. Contact information for the regional CLIA offices can be found at http://www.cms.hhs.gov/clia. The list of laboratories from these sources will be very extensive but can be easily filtered to extract hospital laboratories, independent laboratories, blood banks, public health laboratories, and reference laboratories to produce a shorter list of primary candidates doing HIV-related work. (See Appendix 3 for a CLIA list of types of laboratories.) The CLIA proficiency level given to laboratories may be helpful in

distinguishing between laboratories that conduct HIV testing in-house compared with laboratories that draw the specimen but send it to another laboratory for HIV testing.

- Be aware that states that conduct licensing or credentialing of laboratories within their state often have lists of laboratories and the type of tests they conduct.
- Explore other state programs such as the state Medicaid program, which maintains a list of licensed laboratories that they use for administrative reimbursement purposes.
- Consider other HIV/AIDS surveillance activities—special, new, or existing projects that have established relationships with laboratories and that have created a list of licensed laboratories. Activities to consider include HIV Incidence and Viral Resistance Surveillance and the Morbidity Monitoring Project, especially for identifying laboratories that are not reporting to the HIV/AIDS surveillance program.
- Have field surveillance staff and possibly reporting clinicians review laboratory lists for completeness and accuracy.
- Contact each laboratory and establish a relationship with someone who has a good overview of the entire operation (e.g., laboratory directors); and ask them to complete a survey of what tests they are doing, who serves as their reference laboratory, who are their referring labs, how do they manage their data, what type of IT support do they have, etc.
- Once surveillance staff know where testing is being done, they can start the process of making sure that the laboratories report in some manner, even if it is only on paper.
- The next step is to identify those laboratories that have the capacity to generate and submit electronic files for ELR.
- Be sure to monitor this list routinely as laboratories doing HIV testing may change frequently.

  See Appendix 3 for a list of types of CLIA laboratories and an example of a laboratory survey in Identifying All Reporting Laboratories.

Documentation for Reporting Laboratory

Develop and disseminate laboratory reporting documentation that includes data structure and layout to suit your state's specific needs.

- Because of the complex nature of reporting, make documentation as detailed as possible. It might be beneficial to consult with other states to aid in writing this documentation. Topics to consider include confidentiality and IT issues regarding how data must be formatted and what data elements are required. Alternatively, states may want to approach laboratories with the idea of creating memoranda of understanding (MOUs) itemizing issues on both sides.

- Provide laboratories with a list of tests and test results that are required for each reportable condition.
- Create a data dictionary. Identify and submit to the laboratory a complete listing of fields, data elements, and codes to be used for each lab test and result. The lab results data dictionary is covered in detail in <*Volume II, Data Dictionary*> of *Technical Guidance for HIV/AIDS Surveillance Programs*.
    - Because it is the national standard for laboratories, HL7 is the prototype for the file structure and format that should be encouraged for use in reporting. Some form of documentation on HL7 should be provided in the recommendations. (Keep in mind that HL7 is the standard, but many laboratories are not ready to adopt this standard.)
    - ASCII files should also be accepted with a goal toward transitioning to the HL7 format; the naming conventions, allowable values, and data structures should mimic HL7.
    - Paper reports should continue to be accepted, particularly for low volume laboratories. (These laboratories may not have the resources to convert to an electronic reporting system.)
    - Develop a procedure to follow when a lab transitions its method of reporting from paper to ASCII or HL7, or from ASCII to HL7. The process should involve dual reporting (paper and electronic) and a record-to-record comparison of the data. Do this until the lab has submitted data without error using the new format. All data elements should be compared, but, for higher volume labs, comparison of only a percentage of the records may be the most feasible. This comparison should be conducted over the course of several lab submissions.
- Resolve confidentiality and data transfer/security issues with each laboratory, depending upon its IT capability. Adherence to CDC as well as HIPAA standards for confidentiality and secure data transfer will be required; these standards include encryption before electronic transfer of any confidential surveillance data or information, and are described in Vol. III: Security and Confidentiality Guidelines.
- Establish a reporting schedule: daily, weekly, monthly, etc. Consider lab resources and volume of reports as well as field staff activities in the development of a schedule.
- Consider holding training session(s) for laboratory staff where reporting procedures can be clarified.

  See Appendix 4 for examples of laboratory data elements that should be used for each lab test and result. Two examples of Documentation for Reporting Laboratory have been included.

Alternative Reporting Methods

Offer alternative methods of reporting if a laboratory cannot report electronically or cannot adapt to using your particular system.

- Be aware that laboratories have limits in their own systems.
- Consider an HIV/AIDS-specific electronic method that small laboratories unable to provide reporting through HL7 messaging could use. Some states have created secure Web-based reporting systems for laboratories to manually enter and transfer lab results to surveillance programs. Other states have customized MS-Access databases for laboratories to enter data, encrypt, and transfer these data.

Optional Reports

Depending on your state's regulations, your program may need to develop a method for handling optional reports (e.g., CD4 count ≥200 when state regulations require reporting of CD4 count <200). Unless your regulations prohibit receipt or maintenance of these optional reports, surveillance programs are best served by trying to accommodate all laboratory reporting.

For CD4 counts, it may be impossible for laboratories to exclude CD4 results that are unrelated to HIV/AIDS. In these instances, it will be important to be able to identify cancer treatment facilities in your state. This will allow your program to exclude or prioritize as low this type of optional report that originates from these facilities.

Resolving Referral Laboratory Problems

Determine a mechanism to resolve problems with incomplete data from referral laboratories. This happens most commonly when the testing laboratory indicates the ordering or referral laboratory, but does not include the name of the provider who ordered the test.

- Incomplete data from referral laboratories should be addressed in the writing of the reporting regulations and again when the health department approaches the laboratory about reporting. It is imperative that the accession number or some identifying number that connects the patient with the specimen is preserved. When a specimen has passed from laboratory to laboratory or facility to laboratory, the laboratory actually performing the test should report this identifier. (See Review Reporting Laws.)

Managing Increased Number of Lab Reports

ELR will increase the number of lab results that a surveillance program will need to manage and accurately link to an individual case. An automated system for record linkage may be needed to minimize the number of possible record links that require manual review for final disposition.

- Electronic lab data will likely arrive in a variety of formats. All data of disparate formats must be mapped to a standard format as is being proposed for eHARS. Linking to the registry will be done using the standard format. Procedures for

linking must be developed that include mechanisms for handling links, nonlinks, possible links, and follow-up on both false links and false nonlinks. Strategies for linking and eventual linkage to case reports can be found in the Record Linkage chapter.

- Lab data identifying potential new cases must be communicated with the field staff for completion of the case report form. A secure mechanism for supplying this information to the field staff will need to be implemented. Vol. III: Security and Confidentiality Guidelines includes standards for this kind of intra-program data sharing.

Laboratories First Reporting Electronically

As each laboratory starts a new procedure to report test results electronically (such as switching from paper reports to electronic reports, or shifting reporting responsibility from one group to another), the laboratory should continue to send paper reports until the procedure is well established. Your HIV/AIDS surveillance program should confirm that the compiled line list of paper test reports is the same as the line list of electronic case reports. This can be achieved by manually checking all or a random sample of accession numbers reported manually with the ones reported electronically from the same laboratory. When these two lists agree with each other, your surveillance program can then rely on the completeness of electronic reports from that laboratory and end the receipt of duplicate paper reports.

Reporting Back to Laboratories

Of the 28 areas conducting electronic laboratory reporting, 21 do not report back to laboratories on the quality of data received. (1)

- Develop a procedure for reporting back to laboratories on incomplete reports—an "audit," a "quality control," or a "report card" of sorts. Laboratory feedback should be a goal of the HIV/AIDS surveillance program, and should be modified as resources and experiences dictate. Ongoing communication with laboratories can help to improve accuracy and completeness of reporting the required and recommended data elements. In addition, careful monitoring of laboratory reporting patterns can result in detecting batches of missing reports that can be submitted by the lab in future submissions. Problems of this nature are often identified at the time of laboratory system modifications or staff turnover.

  - Data quality performance indicators that can be reported back to laboratories include completeness, timeliness, data validation, etc. A definition and method for calculating these indicators can be found in Data Quality.

  See Appendix 5 for two examples, (A) and (B), of quality control elements shared with reporting laboratories in Reporting Back to Laboratories.

- Develop and communicate to laboratories a procedure for reporting false-positive reports or lab errors so the surveillance team can update the previous records as appropriate.
  - Laboratories should be interested in false positives and incorrectly reported results. The surveillance program, through other activities, will be identifying inaccurate data and should report these back to the laboratory performing the test. This will involve comparing other surveillance data with laboratory data to obtain an evaluation or accuracy assessment.
    - Example: 'Do the lab data conflict with the data observed in the patient's chart?'
    - Examples of faulty data:
      - very high viral load with no positive HIV diagnostic test result
      - an incorrect HL7 message structure
      - a data entry error on the part of the laboratory
- Depending on the nature and implication of the lab error, the appropriate individuals, both within the surveillance program and laboratory, should be identified and notified.

HIV and HIV-associated Laboratory Tests

Diagnosing HIV Infection

The traditional sequence of laboratory testing for HIV infection relies on detecting antibodies to HIV in the infected person. The initial test (i.e., screening) technology is based on an immunoassay such as enzyme-linked immunosorbent assay (ELISA) or enzyme immunoassay (EIA). The test results are interpreted as either positive (reactive) or negative (nonreactive). When the screening test is repeatedly positive, a confirmatory test such as a Western blot (WB) assay or immunofluorescent antibody (IFA) is then performed. The confirmatory test results are interpreted as positive, negative, or indeterminate. These confirmatory tests use a different technology but again specifically detect antibodies to HIV.

Because the screening and confirmatory tests detect antibodies to HIV, there is a brief window period (usually weeks) in which a person may be HIV-infected but antibodies have not been produced to a level that can be detected by these tests. New testing technology or testing algorithms are being developed to narrow the window period.

Other Tests Indicative of HIV Infection

HIV-1 is the most common HIV type found in the United States. HIV-2 screening and diagnostic tests are also available and have been specified in the detailed test information below. When HIV/AIDS surveillance programs have evidence of an HIV-2 infection, they should contact CDC's HIV/AIDS surveillance branch directly and speak to the coordinator of Cases of Public Health Importance.

Other tests that have been used to diagnose HIV infection include HIV culture (which is unable to distinguish between HIV-1 and HIV-2), HIV-1 P-24 antigen, HIV-1 proviral DNA polymerase chain reaction (PCR), and HIV-1 RNA PCR.

Testing related to HIV incidence and viral resistance (e.g., serologic testing algorithm for recent HIV seroconversion [STARHS] and viral drug resistance) is not covered in this document. Further information about these laboratory tests should be directed to the CDC Incidence and Viral Resistance Team.

HIV Disease Progression and Markers for Access to Care

CD4+ T-lymphocyte tests are used to assess immunosuppression in HIV-infected patients to guide therapeutic decisions. Consequently, CD4 testing at diagnosis and every 3-6 months thereafter is recommended in the management of HIV disease (2). Recent treatment guidance recommends considering antiretroviral therapy when CD4 count is ≤350 cells/µl (2). CD4 results are also used in determining whether an HIV-infected person meets the AIDS immunologic case definition (i.e., CD4 count <200 cells/µl or CD4 percent <14% of total lymphocytes); in 1993, these immunologic criteria were added to the AIDS-defining diseases and conditions (3).

CD4 count, obtained at the time of initial HIV diagnosis, enables the staging of HIV disease. In general, it can be used as an indicator of elapsed time from initial infection to diagnosis: the greater the elapsed time or delay to HIV testing, generally the greater the immunosuppression and the lower the CD4 count. HIV/AIDS programs should make every attempt to collect initial CD4 count (i.e., within 3 months of HIV diagnosis) because the presence and interpretation of CD4 counts reflects whether early HIV testing occurred—from recognition of risky exposures, need for testing, and actual HIV testing—and linkage to care efforts by public health. This may be done by collecting all CD4 counts from laboratories or during case ascertainment field investigations, depending on the resources and structure of each HIV/AIDS surveillance program.

For CD4 reporting, it may be impossible for laboratories to exclude CD4 results that are unrelated to HIV/AIDS (e.g., those that may originate from oncology patients). In these instances, it will be important to be able to identify cancer treatment facilities or cancer treatment providers that may request CD4 testing. This will enable identification of those reports related to HIV disease monitoring.

Viral load monitoring is also important in managing HIV disease care and treatment. Viral load should be obtained at diagnosis and may be a factor in deciding when to initiate antiretroviral therapy (2). A goal of therapy is to reduce viral load levels below the level of test detection (i.e., undetectable viral load result).

Viral load and CD4 testing are also markers of a person's access to care. Furthermore, CD4 testing can be quite specific for HIV disease; >90% of CD4 testing was for HIV-infected persons, as reported by a state conducting HIV/AIDS surveillance (4). Presence of viral load and CD4 test results indicates the patients' clinical status is being monitored, and they are thus receiving some health care. Ongoing testing that meets the current treatment standards is a marker for established, ongoing care and provides some evidence

for the quality of care received. Lack of any viral load or CD4 test result following HIV diagnosis in surveillance data would be interpreted as an unmet health care need and that linkage to care has somehow failed.

Because CD4+ T-lymphocyte and HIV viral load testing are key components of monitoring and managing HIV disease, CDC recommends that all states require laboratory reporting of all levels of CD4 and both detectable and nondetectable viral load results to their state public health departments. Further justification can be found in a CDC-supported Council of State and Territorial Epidemiologists (CSTE) position statement (5).

Changes in Laboratory Reporting Initiated by ELR

Reporting laboratories are encouraged to use the standard HL7 format when transmitting lab result information. (See SNOMED, LOINC, and mapping in Appendix 1 for more information.) Additionally, because of the needs of public health, reporting laboratories have been encouraged to submit information used for surveillance purposes (e.g., race, date of birth, etc.) when available. Furthermore, because of performance characteristic differences between manufacturer-specific tests, HIV/AIDS surveillance programs should collect information that can help distinguish between tests. Viral load testing is an example for which the identification of manufacturer has been recommended as part of standardized reporting (6). Also, as future testing algorithms for HIV diagnosis are introduced, there will be a further need to collect manufacturer and specimen source.

LOINCs have the potential to uniquely identify a clinical test, test method, and specimen source. To avoid the propagation of additional, redundant LOINCs, HIV/AIDS surveillance programs are encouraged to use the LOINCs specified in this document and to propose that laboratories reporting to them also use these unique LOINCs.

See Appendix 6 for a list of LOINCs specific for HIV and HIV-associated testing.

Performance Standards

Performance standards will evolve over time. They are intended to provide a framework of goals and activities that all HIV/AIDS surveillance programs can and should accomplish. Some of the performance standards are goals that programs can use for future planning; others are process standards that programs should strive to meet to ensure local, state, and national data are of high quality.

As electronic lab reports become an increasingly important vehicle for initial case identification, the discriminating information that the lab report contains will be critical to link a lab result to an existing case or to conduct follow-up for a potentially new case.

Case Follow-up from a Lab Report

The flow chart below presents the general outline for receiving laboratory reports, completing investigations when appropriate, and entering data. The initial step is to determine if the laboratory information is sufficiently complete to conduct further steps, to reject the result, or return the information to the laboratory for clarification. The essential elements of any laboratory report include

- the name of the laboratory or CLIA code
- the date of the test (e.g., specimen collection date or date test run)
- the type of test that was conducted, LOINC, or local code
- the test result (which must be a test of interest, i.e., not an incorrectly reported result such as a hepatitis result)
- a patient identifier, such as name, Social Security Number, medical record number, lab accession number, insurance number, Department of Corrections number, coded-identifier or facility-specified identifier
- the name of the physician or clinic ordering the test

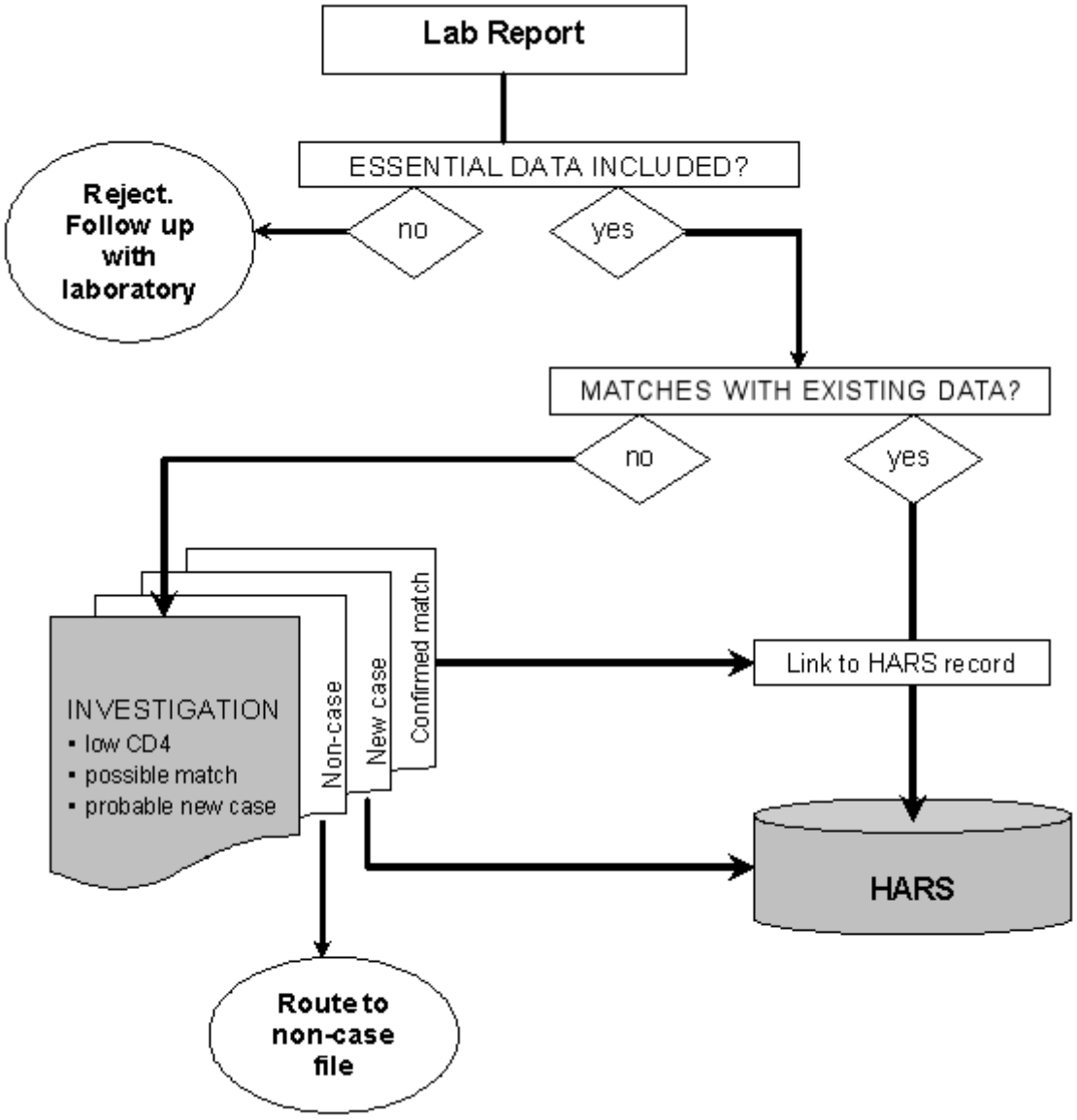
If any of these essential elements are missing, the laboratory needs to be contacted to clarify any missing information. If all of these elements are supplied, then continue and

- Reject certain records based upon the type of test or the test result. If these are results that were not requested, some quality control follow-up is required with the laboratory.
- Contact the provider to obtain information needed to conduct a linkage.
- Link records to determine if the lab result is for an existing case or a potential new case.

Figure 10 depicts the steps taken in follow-up of a lab result. Many details have been omitted for the purpose of generalization.

See Appendix 7 for examples of more detailed program-specific case follow-up flow charts. Three examples—(A), (B), and (C)—of Case Follow-up from a Lab Report have been included.

Figure 10 Lab report follow-up



The Ideal Complete Lab Report

While essential data elements are necessary to keep or reject each individual lab report (Figure 10), the data elements considered essential will differ for each HIV/AIDS surveillance program. In general, an extensive list of variables is recommended for conducting laboratory surveillance. Not all of these variables will be available from all laboratories, but this list may be used as a reference for the ideal laboratory report.

Table 5 includes a list of variables laboratories are strongly encouraged to report because of their value to surveillance. They have been grouped by subject elements, but the relative importance of one field element over another differs for reporting areas. As such, this list should **not** be distributed to laboratories reporting to your surveillance program but appears here for completeness. Your program may choose a subset of these data

elements, depending on your program's needs and priorities. Lists of lab result variables that laboratories should transmit to your program can be found in <*Volume II, Data Dictionary*> or see Appendix 4 for examples of lab data dictionaries in use by surveillance programs.

Table 5 Data elements in an ideal complete lab report

FIELD ELEMENT	Notes	ALTERNATIVE FIELD ELEMENT	Notes
Patient Identifier			
Patient Last Name **Patient First Name** **Patient Middle Name/Middle Initial**		**Elements that comprise state-specific code**	
		OR	
		Medical record number from referral facility	If no referral facility is involved in testing the specimen, this field will be blank.
		Medical record number from testing facility	
		Alternate Patient ID	If an outside laboratory has performed the test, and the referral facility is reporting the result, include the patient identifier from the outside laboratory in this field.
		OR	
		Dept. of Corrections ID	Inmate number
		Insurance or Billing Number	
		Patient Middle Initial	
Patient Social Security Number	Field may be valued as Social Security Number or Railroad Retirement Number.		

Table 5 Data elements in an ideal complete lab report

FIELD ELEMENT	Notes	ALTERNATIVE FIELD ELEMENT	Notes
Patient Demographics			
Patient Date of Birth	Data must be formatted as MM/DD/YYYY (e.g., 12/01/1952).	**Patient Age**	Age at time of first documented HIV+ diagnosis
Patient Gender	Allowable field values are as follows: • Female • Hermaphrodite/ Undetermined • Male • Other • Transsexual • Unknown		
Patient Race	Allowable field values are as follows: • Asian • Black • American Indian or Alaska Native • Multiracial • Other • Pacific Islander • White • Unknown		
Patient Ethnic Group	Allowable field values are as follows: • Hispanic • Non-Hispanic • Unknown		

Table 5 Data elements in an ideal complete lab report

FIELD ELEMENT	Notes	ALTERNATIVE FIELD ELEMENT	Notes
Patient Residence			
Patient Street Address			
Patient County of Residence	If valued, field must be a valid Federal Information Processing Standard (FIPS) code for the patient's county of residence. Valid FIPS county codes by state (as defined by the United States Environmental Protection Agency) can be found at the following Web site: http://www.epa.gov/enviro/html/codes/state.html		
Patient City of Residence		**Patient ZIP Code**	
Patient State of Residence	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt		
Patient Telephone Number			

Table 5 Data elements in an ideal complete lab report

FIELD ELEMENT	Notes	ALTERNATIVE FIELD ELEMENT	Notes
Provider Identification			
Provider Last Name **Provider First Name** **Provider Middle Initial**		**Ordering Facility Name**	
Provider Street Address		**Ordering Facility Street Address**	
Provider City		**Ordering Facility City** ***OR*** **Ordering Facility ZIP**	
Provider State	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt	**Ordering Facility State**	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt
Provider ZIP Code			
Provider Phone Number		**Ordering Facility Phone Number**	
Originating Laboratory (when specimen has been sent to another laboratory for testing, e.g., a specialty laboratory)			
Sending Facility Name	Source of electronic lab report	**Referral Facility Name**	If no referral facility is involved in testing the specimen, this field will be blank.
Sending Facility CLIA	Unique Clinical Laboratory Improvement Amendments Identifier number.		

Table 5 Data elements in an ideal complete lab report

FIELD ELEMENT	Notes	ALTERNATIVE FIELD ELEMENT	Notes
Testing Facility Identification			
Testing Facility Name			
Testing Facility CLIA Code			
Specimen Identification			
Accession Number			
Specimen Received Date	Date specimen received by testing facility. Date field must be formatted as MM/DD/YYYY.		
Specimen Collection Date & Time	Date field must be formatted as MM/DD/YYYY. Time must be formatted as HH:MM (e.g., 12:07) in military time format. Valid values range from 00:00 through 23:59. A blank space should be included between the date and time components (e.g., 10/01/2000 17:42).		
Specimen Analysis Date	Date specimen tested. Date field must be formatted as MM/DD/YYYY.		
Specimen Result Report Date	Date specimen result reported. Data must be formatted as MM/DD/YYYY (e.g., 10/01/2000).		
Specimen Description		**Observation Specimen Source Code**	
		OR	
		Observation Specimen Source Text	

Table 5 Data elements in an ideal complete lab report

FIELD ELEMENT	Notes	ALTERNATIVE FIELD ELEMENT	Notes
Test Identification and Result			
Lab Code		**LOINC Code**	
Lab Code Description		**LOINC Description**	
Manufacturer's Name of Test Kit			
Test Result			
Observation Unit of Measure		**Reference Range**	
Electronic Transmission Identifiers			
Receiving Application	Example of allowable field values are • Bureau of HIV/AIDS • Cancer Registry • Bureau of Communicable Disease Control • Lead Program • Bureau of Sexually Transmitted Diseases • Bureau of Tuberculosis Control		
Lab Report Transmission Date and Time	Data must be formatted as MM/DD/YYYY HH:MM (e.g. 10/01/2000 17:39) with time submitted in military time format. Valid military time values range from 00:00 through 23:59.		
Record Termination Indicator	Field must be valued with 2 exclamation points (!!) to indicate the end of each record.		

Measurable Performance Standards

Because electronic reporting of cases and lab results are relatively new practices to enhance surveillance and not used by all reporting areas, only process standards have been provided in this guideline. Over time, with more experience and as these practices become universal activities to HIV/AIDS surveillance programs, outcome measures may be developed.

Quality of Laboratory Reporting

- HIV/AIDS surveillance programs should send a completeness and data quality "report card" of lab data elements regularly (no fewer than two times a year) to reporting laboratories, meeting a minimum reporting volume.

  For examples of report cards used by surveillance areas, see Appendix 5-B.

- HIV/AIDS surveillance programs should receive batched electronic lab reporting at least monthly. Reporting occurring less frequently than monthly should be followed up by the surveillance program to determine reason for lapse.

Use the report card to indicate

- the total number of records reported by the laboratory
- the number of records containing all of the essential elements outlined in Case Follow-up from a Lab Report
- the number of records that were rejected because they were not appropriate HIV tests or results
- the number of records that were sent back to the laboratory for clarification because not all of the essential elements were supplied

Use the report card to indicate the completeness of the nonessential variables.

- Indicate the completeness (presence) of each variable required by law or regulation.
- Indicate the completeness (presence) of each variable requested by surveillance staff.

Assessing Laboratory Reporting of CD4 and Viral Load Testing

Laboratory testing (i.e., CD4 and viral load) can be used as a marker of entry to receipt of health care. Conversely, the lack of laboratory testing suggests lack of entry to medical care and is an unmet health care need for HIV-infected persons. The completeness of CD4 and viral load reporting will affect its usefulness as a marker of access to health care, and wide variation in area-to-area estimates of access to care will inevitably lead to an understanding of or explanation for the area-to-area variability. Over time and with reporting area participating, national standards may be established.

At least 50% of persons living with HIV/AIDS will have an initial CD4 and/or viral load test results (i.e., within 3 months of diagnosis) reported to the national surveillance system by the HIV/AIDS surveillance program.

Assessing Laboratory Reporting of CD4 Counts Following Initial HIV Diagnosis

Laboratory reporting of CD4 counts serves many surveillance purposes. One use of CD4 reporting is for CD4 count obtained at the time of initial HIV diagnosis to stage HIV disease. Population-based CD4 count at diagnosis has implications for prevention and outreach interventions. Although the actual obtainment of a CD4 count at diagnosis requires health care "intervention" for the ordering of the test, a minimum level of CD4 reporting should be expected for all reporting areas. Areas not able to achieve the minimum level of CD4 reporting may need to investigate surveillance practices and adjust those practices to ensure adequate collection and reporting of CD4 count results.

- Minimum standard:
  - For each calendar year, at least 50% of newly diagnosed persons living with HIV/AIDS, aged ≥13 years, will have an initial CD4 count (i.e., CD4 specimen collected within 3 months of HIV diagnosis) reported to the national HIV/AIDS surveillance system no later than 12 months following diagnosis.
- Optional, additional standards include
  - Determine median and mean CD4 count for persons with
    - HIV without AIDS for >12 months following initial HIV diagnosis
    - HIV that progresses to AIDS 1-12 months following initial HIV diagnosis
    - HIV with AIDS at diagnosis

References

1 2004 Surveillance Coordinators' Survey results. Available with password at http://www2a.cdc.gov/hicsb/. Accessed October 14, 2004.

2 Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents, October 29, 2004. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL10292004002.pdf.

3 Centers for Disease Control and Prevention. 1993 revised classification system for HIV infection and expanded surveillance case definitions for AIDS among adolescents and adults. MMWR 1992; 41: 1-19.

4 Centers for Disease Control and Prevention. Assessment of laboratory reporting to supplement active AIDS surveillance — Colorado. MMWR 1993; 42: 749-752.

5 Council of State and Territorial Epidemiologists. CSTE Position Statement (04-ID-07): Laboratory reporting of clinical test results indicative of HIV infection: new standards for a new era of surveillance and prevention. Available at http://www.cste.org/ps/2004pdf/04-ID-07-final.pdf.

6 Centers for Disease Control and Prevention. Guidelines for laboratory test result reporting of human immunodeficiency virus type 1 ribonucleic acid determination: recommendations from a CDC working group. MMWR 2001;50 (No. RR-20): 1-14. Available at http://www.cdc.gov/mmwr/PDF/RR/RR5020.pdf.

List of Appendices

Appendix 1

Electronic Laboratory Reporting Resources

General Electronic Laboratory Reporting

1. Electronic reporting of laboratory information for public health (1999), 41 pages
http://www.cdc.gov/nedss/ELR/ELR_LabInfo_1999.pdf
Outlines experiences in several states
Includes good descriptions of security issues, encryption, etc.
Main content covers pages 18-32

2. Electronic reporting of lab data for public health (1997), 146 pages
http://www.cdc.gov/nedss/ELR/ELR_LabData_1997.pdf
Summary is on pages 4-6
Background and recommendations are on pages 7-17
Appendices pages 18-145

Health Level 7

3. HL7 specifications, 1997, 70 pages
http://www.cdc.gov/nedss/ELR/HL7Spec.pdf

4. Implementation guide for transmission of laboratory-based reporting of public health information using version 2.3.1 of the Health Level Seven (HL7) standard protocol
http://www.cdc.gov/PHIN/Architecture/Implementation_Guides/Laboratory/PHIN_Laboratory_Result_%20ELR_v231.pdf
This 86-page guide is dated May 2005.

5. Introduction to the Public Health Information Network (PHIN)
http://www.cdc.gov/phin/index.html
This is the CDC/PHIN website. Content ranges from a general overview of PHIN to Functional Requirements and Technical Specifications (Implementation Guides, KPMs, and Data Models).

SNOMED, LOINC, and mapping

6. The National Library of Medicine has developed a Unified Medical Language System metathesaurus which describes both SNOMED and LOINC, and allows you to download each free of charge.
http://www.nlm.nih.gov/research/umls/

7. Description of SNOMED
http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html

8. SNOMED organization home page
http://www.snomed.org/

9. Description of LOINC
http://www.nlm.nih.gov/research/umls/loinc_main.html

10. LOINC, a universal standard for identifying laboratory observations: a 5-year update
http://www.clinchem.org/cgi/content/full/49/4/624?ijkey=oUwNonbF33rao&keytype=ref&siteid=clinchem
This article provides an overview, background, and description of LOINC codes.

11. Regenstrief organization home page
http://www.regenstrief.org/loinc

12. Download of LOINC version 2.13
http://www.regenstrief.org/loinc/download (71 megabyte)
RELMA version 3.13 is also available at this site. RELMA is mapping software for relating local codes to the LOINC database.

13. Introduction to PHIN notifiable condition mapping tables (NCMT, May 2004)
http://www.cdc.gov/PHIN/Vocabulary/Introduction_to_the_PHIN_Notifiable_Condition_Mapping_Tables.doc

13a. Description of LOINC to condition mappings in the PHIN NCMT
http://www.cdc.gov/PHIN/Vocabulary/LOINC_Introduction.doc

13b. Excel table of LOINC to condition mappings, style A
http://www.cdc.gov/phin/vocabulary/LOINC_to_Condition_StyleA.xls
Note there are two options for mapping LOINC codes to conditions. Both styles produce incorrect mappings, but will be updated in 2005. The existing codes are not specific enough for pediatric vs. adult HIV infection vs. AIDS. Style A maps each HIV test to one of the three HIV conditions.

13c. Excel table of LOINC to condition mappings, style B
http://www.cdc.gov/phin/vocabulary/LOINC_to_Condition_StyleB.xls
Style B maps each HIV test to all three HIV conditions.

13d. Description of the SNOMED organism tables in the PHIN NCMT
http://www.cdc.gov/phin/vocabulary/SNOMED_Organism_Lists.doc

13e. SNOMED organism tables
http://www.cdc.gov/phin/vocabulary/SNOMED_Organism_Lists.xls

14. Dwyer tables for mapping organisms to SNOMED codes
http://www.cdc.gov/nedss/DataModels/DWYERIII_SNOMED.pdf

Related Topics

Information about ebXML is available at http://www.ebxml.org/
ebXML (Electronic Business using eXtensible Markup Language) is a modular suite of specifications that enables enterprises of any size and in any geographical location to conduct business over the Internet. Therefore, ebXML is the mechanism or processes by which XML documents can be moved from one business partner to another. Using ebXML, companies now have a standard method to exchange business messages, conduct trading relationships, communicate data in common terms, and define and register business processes.

Published references

McDonald CJ, Huff SM, Suico JG, Hill G, Leavelle D, Aller R, et al. LOINC, a universal standard for identifying laboratory observations: a 5-year update. Clin Chem 2003; 49(4): 624-633.

Wurtz R and Cameron BJ. Electronic laboratory reporting for the infectious disease physician and clinical microbiologist. Clin Infect Dis 2005; 40(1 June): 1638-1643.

Appendix 2

Documentation for Reporting Facilities and Providers

(Appendices 2-A and 2-B)

Appendix 2-A: Fields for HIV and AIDS Reporting by Position

Obs	name	var_type	length	label
1	**ID**	**Character**	**10**	**Patient's ID (at health facility)**
2	**COMPLTED**	**Character**	**10**	**Date initial AIDS/HIV form completed**
3	**SOURCER**	**Character**	**2**	**Source of AIDS report**
4	**HSOURCE**	**Character**	**2**	**Source of HIV report**
5	NAME	Character	45	Name of AIDS case (can be longer to include all text)
6	CPHONE	Character	12	Patient's current phone number (AIDS cases only)
7	SNDX	Character	4	Soundex code for last name
8	BIRTH	Character	10	Date of patient's birth
9	SEX	Character	1	Sex of patient
10	SOCSEC	Character	11	Full Social Security Number for AIDS (xxx xx xxxx); last 4 digits for HIV (xxxx)
11	LAB_NO	Character	15	Lab-generated Accession Number/Lab Report No
12	CT_NO	Character	15	Confidential Counseling &Testing Number
13	**DIAGSTAT**	**Character**	**1**	**Diagnostic Status at Report; 1= HIV; 2=AIDS**
14	**HAGE_YRS**	**Character**	**2**	**Age in years when first found HIV+**
15	**AGE_YRS**	**Character**	**2**	**Age in yrs at dx of AIDS**
16	**STAT**	**Character**	**1**	**Current mortality status**
17	**DEATH**	**Character**	**10**	**Date of patient death**
18	**DEATH_ST**	**Character**	**2**	**State of death**
19	**HISP**	**Character**	**1**	**Patient's Ethnicity (1=Hispanic; 2=non-Hispanic; 9=Unknown)**
20	**RACE_A**	**Character**	**1**	**Race for Asian; 1=yes**
21	**RACE_B**	**Character**	**1**	**Race for Black; 1=yes**
22	**RACE_I**	**Character**	**1**	**Race for American Indian/Alaska Native; 1=yes**
23	**RACE_P**	**Character**	**1**	**Race for Hawaiian/Pacific Islander; 1=yes**
24	**RACE_W**	**Character**	**1**	**Race for White; 1=yes**
25	**RACE_U**	**Character**	**1**	**Race for Unknown; 1=yes**
26	**XRACE**	**Character**	**2**	**Expanded race (see hard copy for codes)**

Obs	name	var_type	length	label
27	**ORIGIN**	**Character**	**1**	**Country or territory of birth (1=US born; 2=foreign born; 9=unk)**
28	**ORIG_OTH**	**Character**	**3**	**Fill this field with XRACE code if not US born**
29	**US_DEPND**	**Character**	**20**	**US dependency where born**
30	**HOMELESS**	**Character**	**1**	**Is the patient homeless at time of AIDS/HIV dx? 1=yes**
31	**RCITY**	**Character**	**27**	**City of residence when AIDS/HIV dx**
32	**ADDRESS**	**Character**	**45**	**Patient's address (AIDS patient only)**
33	**CURR_ST**	**Character**	**2**	**Patient's current state**
34	**CURRCITY**	**Character**	**27**	**Patient's current city**
35	**CURR_ZIP**	**Character**	**9**	**Patient's current ZIP code**
36	**CURRCNTY**	**Character**	**27**	**Patient's current county**
37	**ST**	**Character**	**2**	**State of residence when AIDS dx or when HIV+**
38	**ZIP_CODE**	**Character**	**9**	**ZIP of residence when AIDS dx or when HIV+**
39	**RCOUNTY**	**Character**	**27**	**County of residence at AIDS dx or when HIV+**
40	**RCNTRY**	**Character**	**3**	**Country of residence at AIDS dx or when HIV+**
41	HOSP_DX	Character	27	Facility where AIDS dx
42	HOSP_ST	Character	2	State of facility where AIDS dx
43	HOSP_CTY	Character	27	City of facility where AIDS dx
44	FEDSET	Character	1	Facility setting for AIDS dx
45	FAC_TYPE	Character	2	Type of facility where AIDS dx
46	HHOSP_DX	Character	27	Facility where HIV+
47	HHOSP_ST	Character	2	State of facility where HIV+
48	HHSP_CTY	Character	27	City of facility where HIV+
49	HFEDSET	Character	1	Facility setting for HIV dx
50	HFAC_TYP	Character	2	Type of facility where HIV dx
51	**SEX_MALE**	**Character**	**1**	**Sexual relations with male**
52	**SEX_FMLE**	**Character**	**1**	**Sexual relations with female**
53	**IV**	**Character**	**1**	**IV drug user**
54	**S_IV**	**Character**	**1**	**Sex with IV drug user**
55	**S_BI**	**Character**	**1**	**Sex with bisexual man**
56	**S_HEMO**	**Character**	**1**	**Sex with hemophiliac**
57	**S_TX**	**Character**	**1**	**Sex with transfusion recipient**
58	**S_TRNPLT**	**Character**	**1**	**Sex with transplant recipient**
59	**S_HIV**	**Character**	**1**	**Sex with person with AIDS/HIV**

Obs	name	var_type	length	label
60	**BLDPRD**	**Character**	**1**	**Rec'd blood prod(clotting fac)**
61	**TYP_HEMO**	**Character**	**1**	**Type coagulation disorder**
62	**OTH_HEMO**	**Character**	**2**	**Other coagulation disorder**
63	**TRANSFUS**	**Character**	**1**	**Rec'd blood or blood components**
64	**TRANDTE1**	**Character**	**7**	**Date of first transfusion (mm/yyyy)**
65	**TRANDTE2**	**Character**	**7**	**Date of second transfusion (mm/yyyy)**
66	**TRANPLNT**	**Character**	**1**	**Tissue/transplant recipient**
67	**HCW**	**Character**	**1**	**Patient a health care worker**
68	**OCCUP**	**Character**	**3**	**Patient's hcw occupation**
69	EIA	Character	1	First EIA test
70	EIA_MOYR	Character	7	Date 1st EIA test (mm/yyyy)
71	COMBI	Character	1	First combi test
72	COMBMOYR	Character	7	Date of 1st combi test (mm/yyyy)
73	WBIFA	Character	1	First Western blot test
74	WBMOYR	Character	7	Date of 1st Western blot test (mm/yyyy)
75	HIVAB	Character	2	First other AB test
76	HIVABMOYR	Character	7	Date of 1st other AB test (mm/yyyy)
77	HIVABRES	Character	1	First other AB result
78	HIVDTEST	Character	2	First HIV detection test
79	HIVDMOYR	Character	7	Date 1st HIV detection test (mm/yyyy)
80	HIVDET	Character	1	Result of first HIV detection test
81	HVLOAD	Character	8	Viral load 1 (copies per ml)
82	HVDMOYR	Character	7	DATE FIRST VIRAL LOAD TEST (mm/yyyy)
83	LNEGMOYR	Character	7	Date of last documented negative HIV test (mm/yyyy)
84	LNEGTYPE	Character	2	Specify type of last documented negative HIV test
85	DOC_DIAG	Character	1	If HIV lab test not documented, is HIV diagnosis documented by a physician? 1=yes
86	DOC_MOYR	Character	7	Date of physician's diagnosis of HIV (mm/yyyy)
87	**HIVPMOYR**	**Character**	**7**	**First HIV positive date (mm/yyyy)**
88	TH1CNT	Character	4	Most current CD4 count
89	TH1PCT	Character	2	Most current CD4 percent
90	TH1MOYR	Character	7	Date of most current CD4 test (mm/yyyy)
91	CD4CNT	Character	4	First low CD4 count (<200)
92	CD4PCT	Character	2	First low CD4 percent (<14)
93	CD4MOYR	Character	7	Date of first low CD4 test (mm/yyyy)
94	**REVIEWED**	**Character**	**1**	**Clinical record reviewed**

Obs	name	var_type	length	label
95	**ASYMMOYR**	**Character**	**7**	**Date diagnosed Asymptomatic (mm/yyyy)**
96	**SYMPMOYR**	**Character**	**7**	**Date diagnosed Symptomatic (mm/yyyy)**
97	**CANDLUNG**	**Character**	**1**	**Candidiasis bronchi/lungs/trachea**
98	**CLNGMOYR**	**Character**	**7**	**Dx date for candida bronchi/lungs/trachea (mm/yyyy)**
99	**CANDESOP**	**Character**	**1**	**Candidiasis esophageal**
100	**CESOMOYR**	**Character**	**7**	**Dx date for esophageal candidiasis (mm/yyyy)**
101	**CERVDIS**	**Character**	**1**	**Carcinoma, invasive cervical**
102	**CDISMOYR**	**Character**	**7**	**Dx date for carcinoma cervical (mm/yyyy)**
103	**COCCI**	**Character**	**1**	**Coccidioidomycosis**
104	**CCMOYR**	**Character**	**7**	**Dx date for coccidioidomycosis (mm/yyyy)**

Appendix 2-B: Variables in Order

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
1	NAME	Char	40	1	40	Name of patient	(Last, First, Middle Initial)
2	ADDRESS	Char	40	41	80	Patient's current street address	Street and Number
3	CURRCITY	Char	27	81	107	Patient's current city	For city name, use Table 5
4	CURR_ST	Char	2	108	109	Patient's current state	Abbreviate (such as PA)
5	CURR_ZIP	Char	9	110	118	Patient's current ZIP code	5 digit
6	SSN	Char	11	119	129	Patient's Social Security Number	xxx xx xxxx
7	HCOMPLTD	Char	10	130	139	Date initial HIV+ form compltd	mm/dd/yyyy
8	COMPLTD	Char	10	140	149	Date initial AIDS+ form compltd	mm/dd/yyyy
9	HSOURCE	Char	2	150	151	Source of HIV+ infection report	see Table 1 for code of source
10	SOURCER	Char	2	152	153	Source of AIDS report	see Table 1 for code of source
11	REP_ST	Char	2	154	155	State of report	Abbreviate (such as PA)
12	REP_CITY	Char	27	156	182	City of report	For city name, use Table 5
13	STATENO	Char	10	183	192	State patient number	If available

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
14	CITYNO	Char	10	193	202	Reporting city patient id num	If available
15	DIAGSTAT	Char	1	203	203	Diagnostic Status at Report	1=adult HIV, 2=Adult AIDS
16	BIRTH	Char	10	204	213	Date of patient birth	mm/dd/yyyy
17	STAT	Char	1	214	214	Current mortality status	1=Alive, 2=Dead, 3=Moved, 4=Lost to flwup, 9=Unknown
18	DEATH	Char	10	215	224	Date of patient death	mm/dd/yyyy
19	DEATH_ST	Char	2	225	226	State of death	Abbreviate (such as PA)
20	SEX	Char	1	227	227	Patient's Sex	1=male, 2=female
21	RACE	Char	1	228	228	Patient's Race/Ethnicity	1=White, 2=Black, 4=Asian, 5=Am. Indian, 9=Not specified
22	ETHNIC	Char	1	229	229	Patient's Ethnicity	1=Hispanic, 0=non-Hispanic
23	ORIGIN	Char	1	230	230	Country or territory of birth	1=USA, 2=Canada, 3=Dominican Republic, 4=Haiti, 5=Mexico, 7=US dependency, 8=Other, 9=Unknown
24	US_DEPND	Char	2	231	232	US dependency where born	If you report 7 in Origin, see Table 2 for US Dependency
25	ORIG_OTH	Char	3	233	235	If not US country of birth	If you report 8 in Origin, see Table 3 for other counties
26	HCITY	Char	27	236	262	City of residence when HIV positive	For city name, use Table 5
27	HCOUNTY	Char	27	263	289	County of residence when HIV positive	For county name, use Table 6
28	HST	Char	2	290	291	State of residence when HIV positive	Abbreviate (such as PA)
29	HZIP	Char	9	292	300	ZIP code of residence when HIV positive	5 digit
30	RCITY	Char	27	301	327	City of residence when AIDS dx	For city name, use Table 5

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
31	RCOUNTY	Char	27	328	354	County of residence at AIDS dx	For county name, use Table 6
32	ST	Char	2	355	356	State of residence when AIDS dx	Abbreviate (such as PA)
33	ZIP_CODE	Char	9	357	365	ZIP of residence when AIDS dx	5 digit
34	HFEDSET	Char	1	366	366	Facility setting for HIV dx	1=public, 2=private, 3=federal
35	HFAC_TYP	Char	2	367	368	Type of facility where HIV dx	See Table 1 for type of facility
36	HHOSP_DX	Char	27	369	395	Facility where HIV dx	See Table 4 for facility names
37	HHSP_CTY	Char	27	396	422	City of facility where HIV dx	For city name, use Table 5
38	HHOSP_ST	Char	2	423	424	State of facility where HIV dx	Abbreviate (such as PA)
39	FEDSET	Char	1	425	425	Facility setting for AIDS dx	1=public, 2=private, 3=federal
40	FAC_TYPE	Char	2	426	427	Type of facility where AIDS dx	See Table 1 for type of facility
41	HOSP_DX	Char	27	428	454	Facility where AIDS dx	See Table 4 for facility names
42	HOSP_CTY	Char	27	455	481	City of facility where AIDS dx	For city name, use Table 5
43	HOSP_ST	Char	2	482	483	State of facility where AIDS dx	Abbreviate (such as PA)
44	SEX_MALE	Char	1	484	484	Sexual relations with male	0=No, 1=Yes, 2=CDC Confirmed, 9=Unknown
45	SEX_FMLE	Char	1	485	485	Sexual relations with female	0=No, 1=Yes, 2=CDC Confirmed, 9=Unknown
46	IV	Char	1	486	486	IV drug user	0=No, 1=Yes, 2=CDC Confirmed, 9=Unknown
47	BLDPRD	Char	1	487	487	Rec'd blood prod(clotting fac)	0=No, 1=Yes, 9=Unknown
48	TYP_HEMO	Char	1	488	488	Type coagulation disorder	1=Hemo A, 2=Hemo B
49	OTH_HEMO	Char	2	489	490	Other coagulation disorder	0=No, 1=Yes, 9=Unknown

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
50	S_IV	Char	1	491	491	Sex with IV drug user	0=No, 1=Yes, 9=Unknown
51	S_BI	Char	1	492	492	Sex with bisexual man	0=No, 1=Yes, 9=Unknown
52	S_HEMO	Char	1	493	493	Sex with hemophiliac	0=No, 1=Yes, 9=Unknown
53	S_TX	Char	1	494	494	Sex with transfusion recipient	0=No, 1=Yes, 9=Unknown
54	S_TRNPLT	Char	1	495	495	Sex with transplant recipient	0=No, 1=Yes, 9=Unknown
55	S_HIV	Char	1	496	496	Sex with person with AIDS/HIV	0=No, 1=Yes, 9=Unknown
56	TRANSFUS	Char	1	497	497	Rec'd bld or bld components	0=No, 1=Yes, 2=CDC Confirmed, 9=Unknown
57	TRANDTE1	Char	10	498	507	Date of first transfusion	mm/dd/yyyy
58	TRANDTE2	Char	10	508	517	Date of last transfusion	mm/dd/yyyy
59	TRANPLNT	Char	1	518	518	Tissue/transplant recipient	0=No, 1=Yes, 2=CDC Confirmed, 9=Unknown
60	HCW	Char	1	519	519	Patient a health care worker	0=No, 1=Yes, 9=Unknown
61	EIA	Char	1	520	520	Result of EIA Test	1=Pos, 0=Neg, 9=Not done
62	EIA_MOYR	Char	10	521	530	Date of EIA test	mm/dd/yyyy
63	COMB	Char	1	531	531	Result of HIV1/HIV2 combination test	1=Pos, 0=Neg, 9=Not done
64	COMBMOYR	Char	10	532	541	Date of HIV1/HIV2 combination test	mm/dd/yyyy
65	WBIFA	Char	1	542	542	Result of Western blot	1=Pos, 0=Neg, 9=Not done
66	WBMOYR	Char	10	543	552	Date of Western blot test	mm/dd/yyyy

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
67	HIVAB	Char	2	553	554	Type of other HIV antibody test	01=RIPA, 02=Latex Ag, 03=Peptide, 04=Rapid 11=IgA, 12=IVAP, 88=Other, 99=Unspec
68	HIVABRES	Char	1	555	555	Result of other HIV antibody test	1=Pos, 0=Neg, 9=Not done
69	HVABMOYR	Char	10	556	565	Date of other HIV antibody test	mm/dd/yyyy
70	HIVDTEST	Char	2	566	567	Type of HIV detection test	01=Culture, 02=Antigen, 03=DNA PCR 11=NASBA, 12=RT-PCR, 13=bDNA 14=RNA PCR, 18=Other viral, 88=Other
71	HIVDET	Char	1	568	568	Result of HIV detection test	1=Pos, 0=Neg, 8=Indeterminate
72	HVLOAD	Char	10	569	578	Viral load of HIV detection test (if available)	n=copies/ml
73	HIVDMOYR	Char	10	579	588	Date of HIV detection test	mm/dd/yyyy
74	DOC_DIAG	Char	1	589	589	Physician diagnosis	0=No, 1=Yes, 9=Unknown
75	DOC_MOYR	Char	10	590	599	Date of physician's diagnosis	mm/dd/yyyy
76	CD4CNT	Char	4	600	603	Low CD4 count	number
77	CD4PCT	Char	2	604	605	Low CD4 percent	N=N%
78	CD4MOYR	Char	10	606	615	Date of low CD4 percent	mm/dd/yyyy
79	PHYSNAME	Char	45	616	660	Physician's name	(Last, First, Middle Initial)
80	PPHONE	Char	12	661	672	Physician's phone number	xxx-xxx-xxxx
81	MEDRECNO	Char	14	673	686	Medical record number	
82	PERS_COM	Char	24	687	710	Person completing form	(Last, First, Middle Initial)
83	COMPHONE	Char	12	711	722	Interviewer's phone number	xxx-xxx-xxxx

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
84	REVIEWED	Char	1	723	723	Clinical record reviewed	0=No, 1=Yes
85	ASYMMOYR	Char	10	724	733	Date diagnosed Asymptomatic	mm/dd/yyyy
86	SYMPMOYR	Char	10	734	743	Date diagnosed Symptomatic	mm/dd/yyyy
87	CANDLUNG	Char	1	744	744	Candidiasis lungs	1=definitive, 0=not diagnosis
88	CLNGMOYR	Char	10	745	754	Dx date for candida lungs/trac	mm/dd/yyyy
89	CANDESOP	Char	1	755	755	Candidiasis esophageal	1=definitive, 2=presumptive, 0=not diagnosis
90	CESOMOYR	Char	10	756	765	Dx date for esophageal candida	mm/dd/yyyy
91	CERVDIS	Char	1	766	766	Carcinoma cervical	1=definitive, 0=not diagnosis
92	CDISMOYR	Char	10	767	776	Dx date for carcinoma cervical	mm/dd/yyyy
93	COCCI	Char	1	777	777	Coccidioidomycosis	1=definitive, 0=not diagnosis
94	CCMOYR	Char	10	778	787	Dx date for coccidioidomycosis	mm/dd/yyyy
95	CRYPTOCO	Char	1	788	788	Cryptococcosis	1=definitive, 0=not diagnosis
96	CTCCMOYR	Char	10	789	798	Dx date for cryptococcosis	mm/dd/yyyy
97	CRYPTOSP	Char	1	799	799	Cryptosporidiosis	1=definitive, 0=not diagnosis
98	CRYPMOYR	Char	10	800	809	Dx date for cryptosporidiosis	mm/dd/yyyy
99	CMV	Char	1	810	810	Cytomegalovirus disease	1=definitive, 0=not diagnosis
100	CMVMOYR	Char	10	811	820	Dx date for cytomegalovirus	mm/dd/yyyy
101	CMVRET	Char	1	821	821	Cytomegalovirus retinitis	1=definitive, 0=not diagnosis
102	CMVRMOYR	Char	10	822	831	Dx date for CMV retinitis	mm/dd/yyyy
103	DEMENTIA	Char	1	832	832	HIV encephalopathy	1=definitive, 0=not diagnosis
104	DEMMOYR	Char	10	833	842	Dx date for HIV encephalopathy	mm/dd/yyyy
105	HS	Char	1	843	843	Chronic mucocutaneous herpes	1=definitive, 0=not diagnosis

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
106	HSMOYR	Char	10	844	853	Dx date for chronic herpes	mm/dd/yyyy
107	HISTO	Char	1	854	854	Histoplasmosis	1=definitive, 0=not diagnosis
108	HISTMOYR	Char	10	855	864	Dx date for histoplasmosis	mm/dd/yyyy
109	ISO	Char	1	865	865	Isosporiasis	1=definitive, 0=not diagnosis
110	ISOMOYR	Char	10	866	875	Dx date for isosporiasis	mm/dd/yyyy
111	KS	Char	1	876	876	Kaposi's sarcoma	1=definitive, 2=presumptive, 0=not diagnosed
112	KSMOYR	Char	10	877	886	Dx date for Kaposi's sarcoma	mm/dd/yyyy
113	BURKL	Char	1	887	887	Burkitt's lymphoma	1=definitive, 0=not diagnosis
114	BURKMOYR	Char	10	888	897	Dx date for Burkitt's lymphoma	mm/dd/yyyy
115	IBL	Char	1	898	898	Immunoblastic lymphoma	1=definitive, 2=presumptive, 0=not diagnosed
116	IBLMOYR	Char	10	899	908	Dx date for immunoblastic lymp	mm/dd/yyyy
117	PLB	Char	1	909	909	Primary lymphoma of brain	1=definitve, 0=not diagnosed
118	PLBMOYR	Char	10	910	919	Dx date for lymphoma of brain	mm/dd/yyyy
119	MAVIUM	Char	1	920	920	Mycobacterium avium complex	1=definitive, 2=presumptive, 0=not diagnosed
120	MAVMOYR	Char	10	921	930	Dx date for M. avium complex	mm/dd/yyyy
121	PULM_TB	Char	1	931	931	Pulmonary TB	1=definitive, 2=presumptive, 3=Pre 93 Result, 0=not diagnosed
122	PTBMOYR	Char	10	932	941	Date of pulmonary TB diagnosis	mm/dd/yyyy
123	TB	Char	1	942	942	M. tuberculosis	1=definitive, 2=presumptive, 0=not diagnosed
124	TBMOYR	Char	10	943	952	Dx date for M. tuberculosis	mm/dd/yyyy
125	MYCO	Char	1	953	953	Atypical mycobact diagnosed	1=definitve, 2=presumptive, 0=not diagnosed

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
126	MYCOMOYR	Char	10	954	963	Dx date for atypical mycobact.	mm/dd/yyyy
127	PC	Char	1	964	964	Pneumocystis carinii pneumonia	1=definitive, 2=presumptive, 9=unknown
128	PCMOYR	Char	10	965	974	Dx date for pneumocystis pneu.	mm/dd/yyyy
129	RP	Char	1	975	975	Pneumonia recurrent	1=definitive, 2=presumptive, 0=not diagnosed
130	RPMOYR	Char	10	976	985	Dx date for pneu. recurrent	mm/dd/yyyy
131	PML	Char	1	986	986	Progress multifoc leukoenceph	1=definitive, 0=not diagnosed
132	PMLMOYR	Char	10	987	996	Dx date for multifoc. leuko.	mm/dd/yyyy
133	SALS	Char	1	997	997	Salmonella septicemia	1=definitive, 0=not diagnosed
134	SALSMOYR	Char	10	998	1007	Dx date for salmonella sept.	mm/dd/yyyy
135	TP	Char	1	1008	1008	Toxoplasmosis of brain	1=definitive, 2=presumptive, 0=not diagnosed
136	TPMOYR	Char	10	1009	1018	Dx date for toxoplasmosis	mm/dd/yyyy
137	WASTING	Char	1	1019	1019	Wasting syndrome	1=definitive, 0=not diagnosis
138	WASTMOYR	Char	10	1020	1029	Dx date for wasting syndrome	mm/dd/yyyy
139	RVCTNO	Char	9	1030	1038	RVCT Case Number	
140	OTH_IMM	Char	1	1039	1039	Other immunodeficiency would disqualify AIDS	0=No, 1=Yes, 9=Unknown
141	INFORMED	Char	1	1040	1040	Patient informed of HIV	0=No, 1=Yes, 9=Unknown
142	NOTIFIED	Char	1	1041	1041	Patient's partners notified by	1=Health Dept., 2=Provider, 3=Patient, 9=Unknown
143	REF_MS	Char	1	1042	1042	Referred for medical service	0=No, 1=Yes, 9=Unknown
144	REF_SATS	Char	1	1043	1043	Refer for substance abuse Rx	1=Yes, 0=No, 8=N/A, 9=Unknown

Order	Variable	Typ	Len	lenbegin	lenend	Label	Format
145	ANTIRETV	Char	1	1044	1044	Rec'd antiretroviral Rx	0=No, 1=Yes, 9=Unknown
146	PCPPROPH	Char	1	1045	1045	Receive PCP prophylaxis?	0=No, 1=Yes, 9=Unknown
147	TRIAL	Char	1	1046	1046	Patient enrolled in trial	1=NIH sponsored, 2=Other, 3=None, 9=Unknown
148	CLINIC	Char	1	1047	1047	Patient enrolled in clinic	1=HRSA sponsored, 2=Other, 3=None, 9=Unknown
149	INSURNCE	Char	1	1048	1048	Patient's insurance type	1=Medicaid, 2=Private Coverage, 3=No Coverage, 4=Other public fund, 7=Gov't program 9=Unknown
150	PRENATAL	Char	1	1049	1049	Patient-received OB/GYN service	0=No, 1=Yes, 9=Unknown
151	PREGNANT	Char	1	1050	1050	Patient currently pregnant	0=No, 1=Yes, 9=Unknown
152	LIVE_INF	Char	1	1051	1051	Patient delivered live infant	1=Yes, 0=No, 9=Unknown
153	CBDATE	Char	10	1052	1061	Child's birthdate	mm/dd/yyyy
154	CHOSP	Char	27	1062	1088	Hospital of child birth	See Table 4 for facility names
155	CHCITY	Char	27	1089	1115	City of hosp of child's birth	For city name, use Table 5
156	CHOSP_ST	Char	2	1116	1117	State of hosp of child's birth	Abbreviate (such as PA)
157	CSTATENO	Char	10	1118	1127	Child's state patient no.	If available
158	COMMENT1	Char	65	1128	1192	First line of comments	Any comments for DOH

Note:
1. Variable names in the list are names used in the CDC database.
2. We hope that providers submit the data to us in the same order of variables and in the same length and format for each variable.
3. If an observation does not have any value for a variable, please just leave it empty.
4. All dates should be in the format of mm/dd/yyyy, such as 10/18/2002.
5. Please send an ASCII, HL7, or Excel file, or use PA EPI_INFO database.

Appendix 3

Identifying All Reporting Laboratories

Provider Type Information

CLIA Laboratories

01 Ambulatory Surgery Center
02 Community Clinic
03 Comprehensive Outpatient Rehab
04 Ancillary Test Site
05 ESRD (End Stage Renal Disease Dialysis)
06 Health Fair
07 HMO
08 Home Health Agency
09 Hospice
10 Hospital
11 Independent Laboratory
12 Industrial
13 Insurance
14 Intermediate Care Facility - Mentally Retarded
15 Mobile Unit
16 Pharmacy
17 School/Student Health Service
18 Skilled Nursing/Nursing Facility
19 Physician Office
20 Other Practitioner
21 Tissue Bank/Repositories
22 Blood Banks
23 Rural Health Clinic/Federally Qualified Health Center
24 Ambulance
25 Other

Laboratory Surveillance Survey Questions

Laboratory Name_____

Laboratory Contact_____

Address_____

_____**ZIP Code**_____

Phone_____

Fax_____

E-mail_____

(Circle the Most Appropriate)	**Type of Laboratory**	
Public	**Private**	**Federal**
Hospital	Hospital	Hospital
Clinic	Blood Bank	Clinic
Other: Specify Below>	Physician – POL	Other: Specify Below>
	Reference Laboratory	

I. Data Management

1. Please indicate which of the following your laboratory has available for each lab procedure performed.

Data Element	Yes	No
Patient's Name		
Patient's Address		
Date of Birth		
Sex		
Race		
Provider's Name		
Provider's Phone Number		
Doctor's Name		
Medical Record Number		
Social Security Number		

2. Indicate your method of data maintenance. If you are using more than one method, indicate all that apply.

Data Maintenance	Yes	No
Computer File		
Log Book		
Paper File of Lab Slips		
Other _____		

3. If you are using a Laboratory Information System, provide the name of the vendor as well as the name of the person(s) within your lab/institution who is responsible for maintaining the system.

Vendor_____

Information System Manager_____

4. Are you familiar with the HL7 data format for the electronic exchange of health care related information? Yes No

5. Would your laboratory be interested in serving as a pilot for the testing of software to automate the reporting of communicable disease data?
Yes No

II. Human Immunodeficiency Virus Testing

6. Does your laboratory perform any rapid test for HIV detection?

Yes No

If you are doing rapid tests, please give the name of the test you are using_____.

7. Does your laboratory perform any of the following HIV tests in house? Check all that you are currently performing.

❏ Human Immunodeficiency Virus (HIV) EIA Screen
❏ HIV Western Blot
❏ HIV DNA by ❏bDNA or ❏PCR
❏ HIV RNA by ❏bDNA or ❏PCR
❏ HIV Resistance Testing: ❏ Genotype, ❏ Phenotype
❏ HIV P24 Antigen
❏ HIV Culture
❏ CD4+ Counts

8. Reference Laboratories: Do you use a Reference Laboratory(s) to assist your facility with testing for human immunodeficiency virus? If so please indicate the specific test, the lab's name and phone number, and the name of the contact person. If you are using multiple reference laboratories, please provide the information requested below for each.

Reference Lab #1_____
Test(s)_____
Name of Contact Person_____
Phone Number_____

Reference Lab#2_____
Test(s)_____
Name of Contact Person_____
Phone Number_____

Reference Lab#3_____
Test(s)_____
Name of Contact Person_____
Phone Number_____

Appendix 4

Documentation for Reporting Laboratory

Data Record Layout

ID No	Field Description	Length	Optional/ REQUIRED	Variable Type	Notes
1.	Medical record number from referral facility	16	Optional	Character	If no referral facility is involved in testing the specimen, this field will be blank.
2.	Referral Facility Name	30	Optional	Character	If no referral facility is involved in testing the specimen, this field will be blank.
3.	Medical record number from testing facility	20	REQUIRED	Character	
4.	Testing Facility CLIA Code	10	Optional	Character	
5.	Alternate Patient ID	16	Optional	Character	If an outside laboratory has performed the test, and the referral facility is reporting the result, include the patient identifier from the outside laboratory in this field.
6.	Patient Last Name	48	REQUIRED	Character	
7.	Patient First Name	48	REQUIRED	Character	
8.	Patient Middle Name	48	Optional	Character	
9.	Patient Name Suffix	48	Optional	Character	
10.	Patient Date of Birth	10	REQUIRED	Character	Data must be formatted as MM/DD/YYYY (e.g., 12/01/1952).
11.	Patient's Age	20	Optional	Numeric	
12.	Patient's Place of Birth	1	Optional	Character	Allowable field values are as follows: 0 = Patient was Foreign Born 1 = Patient was born in the US
13.	Patient's Country of Origin	30	Optional	Character	
14.	Patient's Length of Residency in the US	6	Optional	Character	Submit as the number of years and months the patient has been a resident of the United States. Field should be formatted as follows: YY MM (e.g. 12 08 = A resident of the US for 12 years and 8 months)

ID No	Field Description	Length	Optional/ REQUIRED	Variable Type	Notes
15.	Patient's Race	1	Optional	Character	Allowable field values are as follows: A = Asian or Pacific Islander B = Black I = American Indian or Alaska Native M = Multiracial O = Other U = Unknown W = White
16.	Patient's Ethnic Group	1	Optional	Character	Allowable field values are as follows: H = Hispanic N = Non-Hispanic U = Unknown
17.	Patient's Gender	1	Optional	Character	Allowable field values are as follows: F = Female H = Hermaphrodite/Undetermined M = Male O = Other T = Transsexual U = Unknown
18.	Patient's Street Address	62	REQUIRED	Character	
19.	Patient's City	30	REQUIRED	Character	
20.	Patient's State	2	REQUIRED	Character	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt
21.	Patient's Country of Residence	3	Optional	Character	
22.	Patient's ZIP Code	9	REQUIRED	Character	
23.	Patient's County of Residence	20	Optional	Character	If valued, field must be a valid Federal Information Processing Standard (FIPS) code for the patient's county of residence. Valid FIPS county codes by state (as defined by the United States Environmental Protection Agency) can be found at the following Web site: http://www.epa.gov/enviro/html/codes/state.html

ID No	Field Description	Length	Optional/ REQUIRED	Variable Type	Notes
24.	Patient's Telephone Number	40	Optional	Character	
25.	Patient's Social Security Number	16	Optional	Character	Field may be valued as Social Security Number or Railroad Retirement Number. Social Security Number should be reported for cancer results only.
26.	Parent's Last Name	25	Optional	Character	
27.	Parent's First Name	20	Optional	Character	
28.	Parent's Middle Initial	1	Optional	Character	
29.	Parent's Name Suffix	2	Optional	Character	
30.	Parent's Street Address	62	Optional	Character	
31.	Parent's City	30	Optional	Character	
32.	Parent's State	2	Optional	Character	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt
33.	Parent's Country	3	Optional	Character	If valued, recommend using valid Universal Postal Union country abbreviations code, ISO3166 Alpha-3 standard as detailed at the following Web site: http://www.upu.int/upu/AN/Pays_membres.html
34.	Parent's ZIP Code	9	Optional	Character	
35.	Parent's Phone Number	40	Optional	Character	
36.	Pregnancy Flag	1	Optional	Character	Allowable field values are as follows: Y = Patient is Pregnant N = Patient is not Pregnant
37.	Dept. of Corrections ID	7	Optional	Character	Inmate number
38.	Insurance or Billing Number	20	Optional	Character	

ID No	Field Description	Length	Optional/ REQUIRED	Variable Type	Notes
39.	Type of Insurance	1	Optional	Character	Allowable field values are as follows: 1 = Patient is Self-Insured 2 = Blue Cross 3 = Commercial Insurer 4 = Medicaid 5 = Medicare 6 = CHAMPUS 7 = Managed Care Plan
40.	Vaccine Trial Participation	1	Optional	Character	Allowable field values are as follows: 0 = Participated in vaccine trial 1 = Did not participate in vaccine trial
41.	Provider Last Name	25	Optional	Character	
42.	Provider First name	20	Optional	Character	
43.	Provider Middle Initial	1	Optional	Character	
44.	Provider Name Suffix	2	Optional	Character	
45.	Provider Street Address	62	Optional	Character	
46.	Provider City	30	Optional	Character	
47.	Provider State	2	Optional	Character	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt
48.	Provider ZIP Code	9	Optional	Character	
49.	Provider Phone Number	40	Optional	Character	
50.	Ordering Facility Name	40	Optional	Character	
51.	Ordering Facility Street	62	Optional	Character	
52.	Ordering Facility City	30	Optional	Character	
53.	Ordering Facility State	2	Optional	Character	If valued, field must be a valid USPS state abbreviation code to identify the state of residence. Valid state codes (as defined by the United States Postal Service) can be found at the following Web site: http://www.usps.com/ncsc/lookups/abbr_state.txt
54.	Ordering Facility ZIP	9	Optional	Character	

ID No	Field Description	Length	Optional/ REQUIRED	Variable Type	Notes
55.	Ordering Facility Phone Number	40	Optional	Character	
56.	Pathologist Name	178	Optional	Character	
57.	Pathologist License Number	20	Optional	Character	
58.	Pathologist State of License	2	Optional	Character	
59.	Accession Number	75	Optional	Character	
60.	SNOMED Code	200	Optional	Character	Valued with type of analysis performed.
61.	Observation Date & Time	16	Optional	Character	Date field must be formatted as MM/DD/YYYY. Time must be formatted as HH:MM (e.g. 12:07) in military time format. Valid values range from 00:00 through 23:59. A blank space should be included between the date and time components (e.g., 10/01/2000 17:42).
62.	Observation Specimen Source Code	8	Optional	Character	
63.	Observation Specimen Source Text	40	Optional	Character	
64.	Result Report Date	10	Optional	Character	Data must be formatted as MM/DD/YYYY (e.g., 10/01/2000).
65.	Result Status Code	1	Optional	Character	Allowable field values are as follows: C = Correction to results F = Final result
66.	Data Type	2	Optional	Character	
67.	LOINC Code	10	Optional	Character	
68.	LOINC Description	50	Optional	Character	
69.	Lab Code	10	REQUIRED	Character	
70.	Lab Code Description	50	REQUIRED	Character	
71.	Observation Unit of Measure	60	Optional	Character	
72.	Reference Range	10	Optional	Character	
73.	Observation Result Status	1	Optional	Character	
74.	Observation Method	60	Optional	Character	
75.	Test Result	100	REQUIRED	Character	

ID No	Field Description	Length	Optional/ REQUIRED	Variable Type	Notes
76.	Path Report	48000	Optional	Character	
77.	SNOMED Code	10	Optional	Character	
78.	Specimen Description	4000	Optional	Character	
79.	ICD Code	10	Optional	Character	
80.	ICD Rev No	10	Optional	Character	
81.	Clinical History	4000	Optional	Character	
82.	Nature of Specimen	4000	Optional	Character	
83.	Gross Pathology	4000	Optional	Character	
84.	Microscopic Pathology	4000	Optional	Character	
85.	Final DX	4000	Optional	Character	
86.	Comment	4000	Optional	Character	
87.	Supplemental Reports	4000	Optional	Character	
88.	Staging Parameters	4000	Optional	Character	
89.	Sending Facility Name	170	REQUIRED	Character	
90.	Sending Facility CLIA	10	REQUIRED	Character	Unique Clinical Laboratory Improvement Amendment Identifier number.
91.	Message Date and Time	26	REQUIRED	Character	Data must be formatted as MM/DD/YYYY HH:MM (e.g., 10/01/2000 17:39) with time submitted in military time format. Valid military time values range from 00:00 through 23:59.
92.	Receiving Application	60	Optional	Character	Allowable field values are as follows: AIDS = Bureau of HIV/AIDS CANCER = Cancer Registry CD = Bureau of Communicable Disease Control LEAD = Lead Program STD = Bureau of Sexually Transmitted Diseases TB = Bureau of Tuberculosis Control
93.	Record Termination Indicator	2	REQUIRED	Character	Field must be valued with 2 exclamation points (!!) to indicate the end of each record.

Sample ASCII File Data Record

||MR40155|33D1234567||Duck|Daffy||Jr.|10/10/1966||1|USA||O|U|T|211 LaLa Land|Binghamton|NY|USA|13901|7|607.754.5454|122-33-4556|||||||||||||||ProviderLastName|ProviderFirstName|||212 Central Avenue|Albany|NY|12201|518.432.3209 X247|General Hospital|9 East Overshoot Drive Street|Gloversville|NY|12078|518.999.9999|Dr. Shiny Diamond||NY|Accession#10117||10/09/2000 12:07|Throat|Throat|10/09/2000 12:07|F||6819-7|Streptococcus AB|Strep AB|Streptococcus AB|CELLS/UL|Reference Range|||Positive for Strep Culture. Variant AB.||SNOMED Code||ICD Code|ICD Rev Code|Clinical History|Nature of Specimen|Gross Pathology|Microscopic Pathology|Final DX|Comments|Supplemental Reports|Staging Parameters|General Hospital|33D9999999|10/09/2000 11:01|CD|!!

Appendix 5

Reporting Back to Laboratories

Appendix 5-A

Standardized ASCII Format for Electronic Laboratory Reporting

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This document provides a standardized ASCII format for morbidity records reported by laboratories participating in Electronic Laboratory Reporting (ELR). A standardized ASCII format will facilitate importation of morbidity data into specific database applications maintained by the Texas Department of Health's Bureau of HIV/STD Prevention and will allow for dissemination of these data to local health authorities on a daily basis.

A. General Requirements

1. Date fields may be represented in the following format: MM/DD/YYYY.

2. Telephone numbers may be represented in either XXX-XXX-XXXX or XXXXXXXXXX format.

3. Social Security Number may be represented in either XXX-XX-XXXX or XXXXXXXXX format.

B. Data Variables

Patient ID **Must be defined in the file, but may be missing in the records that are provided**.
Up to 20 characters.

Last Name **Must be defined in the file and must be present in the records that are provided**.
Up to 20 characters.

First Name **Must be defined in the file and must be present in the records that are provided**.
Up to 20 characters.

MI **Must be defined in the file, but may be missing in the records that are provided**.
One (1) character.

DOB **Must be defined in the file, but may be missing in the records that are provided**.
Ten (10) characters.

Age **Must be defined in the file, but may be missing in the records that are provided**.
Up to 3 numbers.

SSN **Must be defined in the file, but may be missing in the records that are provided**.
Nine (9) or eleven (11) characters, depending on the SSN format.

Sex **Must be defined in the file, but may be missing in the records that are provided**.
Seven (7) characters.

Race **Must be defined in the file, but may be missing in the records that are provided**.
One (1) character.

Ethnicity **Must be defined in the file, but may be missing in the records that are provided**.
One (1) character.

Street **Must be defined in the file, but may be missing in the records that are provided**.
Up to 30 characters.

City **Must be defined in the file, but may be missing in the records that are provided**.
Up to 20 characters.

County **Must be defined in the file, but may be missing in the records that are provided**.
Up to 20 characters.

State **Must be defined in the file, but may be missing in the records that are provided**.
Two (2) characters.

ZIP **Must be defined in the file, but may be missing in the records that are provided**.
A 5-character field.

Phone **Must be defined in the file, but may be missing in the records that are provided**.
Ten (10) or 12 characters, depending on format.

Provider ID **Must be defined in the file, but may be missing in the records that are provided**.
Up to 20 characters.

Provider **Must be defined in the file and must be present in the records that are provided**.
Up to 30 characters.

Accession **Must be defined in the file and must be present in the records that are provided**.
Up to 15 characters.

PrCity **Must be defined in the file and must be present in the records that are provided**.
Up to 20 characters.

PrCounty **Must be defined in the file, but may be missing in the records that are provided**.
Up to 20 characters.

PrPhone **Must be defined in the file, but may be missing in the records that are provided**.
Ten (10) or 12 characters, depending on format.

PrState **Must be defined in the file, but may be missing in the records that are provided**.
Two (2) characters.

PrZIP **Must be defined in the file and must be present in the records that are provided**.
A 5-character field.

Collected **Must be defined in the file, but may be missing in the records that are provided**.
Ten (10) characters.

Received **Must be defined in the file, but may be missing in the records that are provided**.
Ten (10) characters.

Reported **Must be defined in the file and must be present in the records that are provided**. Ten (10) characters.

Specimen **Must be defined in the file, but may be missing in the records that are provided**. Up to 20 characters.

Lab ID **Must be defined in the file and must be present in the records that are provided**. Up to 10 characters.

Analysis **Must be defined in the file, but may be missing in the records that are provided**. Ten (10) characters.

Test Type **Must be defined in the file and must be present in the records that are provided.** Up to 30 characters.

Qual Resul **Must be defined in the file and must be present in the records that are provided. (if qualitative results are appropriate for the test type)**. Up to 15 characters.

Quan Resul **Must be defined in the file and must be present in the records that are provided. (if quantitative results are appropriate for the test type)**. Up to 15 characters.

Units **Must be defined in the file, but may be missing in the records that are provided**. Up to 15 characters.

Ref Range **Must be defined in the file, but may be missing in the records that are provided**. Up to 15 characters.

C. Record Layout

The following record layout is recommended for all ASCII files received from ELR participating laboratories:

VARIABLE	POSITION	LENGTH	RECORD TYPE
PATIENT ID	1 - 20	20	PATIENT
LAST NAME	21 - 40	20	PATIENT
FIRST NAME	41 - 60	20	PATIENT
MI	61	1	PATIENT
DOB	62 - 71	10	PATIENT
AGE	72 - 74	3	PATIENT
SSN	75 - 85	11	PATIENT
SEX	86 - 92	7	PATIENT
RACE	93	1	PATIENT
ETHNICITY	94	1	PATIENT
STREET	95 - 125	30	PATIENT
CITY	126 -146	20	PATIENT
STATE	147 - 148	2	PATIENT
ZIP	149 - 153	5	PATIENT
PHONE	154 - 165	12	PATIENT
PROVIDER ID	166 - 186	20	SPECIMEN
PROVIDER	187 - 217	30	SPECIMEN
ACCESSION	218 - 233	15	SPECIMEN
PRCITY	234 - 254	20	SPECIMEN
PRCOUNTY	255 - 275	20	SPECIMEN
PRPHONE	276 - 287	12	SPECIMEN
PRSTATE	288 - 289	2	SPECIMEN
PRZIP	290 - 294	5	SPECIMEN

VARIABLE	POSITION	LENGTH	RECORD TYPE
COLLECTED	295 - 305	10	SPECIMEN
RECEIVED	306 - 315	10	SPECIMEN
REPORTED	316 - 325	10	SPECIMEN
SPECIMEN	326 - 346	20	SPECIMEN
LAB ID	347 - 357	10	TEST
ANALYSIS	358 - 368	10	TEST
TEST TYPE	369 - 399	30	TEST
QUAL RESUL	400 - 414	15	TEST
QUAN RESUL	415 - 429	15	TEST
UNITS	430 - 444	15	TEST
REF RANGE	445 - 459	15	TEST

D. Data Dictionary

FIELD NAME	LENGTH	DESCRIPTION/CODED VALUES	REQUIRED
Patient ID	20	Laboratory system-generated patient ID	Y
Last Name	20	Patient last name	Y
First Name	20	Patient first name	
MI	1	Patient middle initial	
DOB	10	Patient date-of-birth	
Age	3	Patient age at testing	
SSN	9	Patient Social Security Number	
Sex	7	Patient gender: **Male** **Female** **Unknown**	
Race	1	Patient race: (race codes) **1 = American Indian/Alaska Native** **2 = Asian/Pacific Islander** **3 = Black** **4 = White** **5 = Other** **9 = Unknown**	
Ethnicity	1	Patient ethnicity: (ethnicity codes) **1 = Hispanic** **2 = Non-Hispanic** **9 = Unknown**	
Street	30	Patient street address	
City	20	Patient city of residence	
County	20	Patient county of residence	
State	2	Patient state of residence	
ZIP	5	Patient ZIP code	
Phone	10	Patient telephone number	
Provider ID	20	Laboratory system-generated provider ID	
Provider	30	Provider name	Y

FIELD NAME	LENGTH	DESCRIPTION/CODED VALUES	REQUIRED
Accession	15	Laboratory system-generated order of aquisition	Y
PrCity	20	Provider city	Y
PrCounty	20	Provider county	
PrPhone	10	Provider telephone number	
PrState	2	Provider state	
PrZIP	5	Provider ZIP code	Y
Collected	10	Date of specimen collection	
Received	10	Date specimen received by laboratory	
Reported	10	Date results reported to Public Health	Y
Specimen	20	Anatomical site where specimen obtained	
Lab ID	10	Name of reporting laboratory	Y
Analysis	10	Date of specimen analysis	
Test Type	30	Type of test	Y
Qual Resul	15	Qualitative result: (i.e.) **Positive** **Reactive** **Negative** **Nonreactive** **Indeterminate** **Contaminated**	Y
Quan Resul	15	Quantitative result	Y
Units	15	Qualifier for quantitative result	
Ref Range	15	Reference range for test performed	

HIV Laboratory Reporting Summary

For the period January – June 2003

	Your Lab		All Labs (N=20)	
Volume of Test Data				
CD4	131		3,368	
CD4 %	132		3,440	
Western Blot	111		461	
Viral Load	167		6,317	
Completeness of Information				
Name*	541	100% Complete	11,578	100% complete
Date of Birth*	534	99% Complete	10,681	92% complete
Age*	534	99% Complete	1,588	14% complete
Gender*	538	99% Complete	11,202	96% complete
Last 4 digits of Social Security Number*	0	0% Complete	5,215	45% complete
Patient ID#	495	91% Complete	8,114	70% complete
Specimen Collection Date*	541	100% Complete	11,575	100% complete

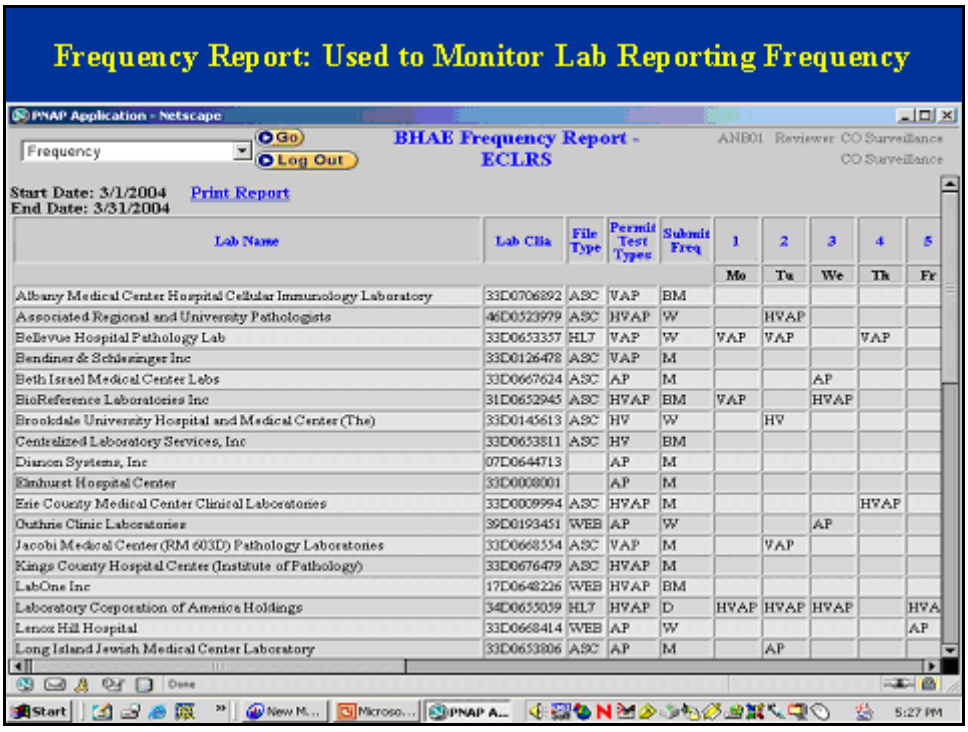
* Required component of Washington HIV reports

Data Transmission Details

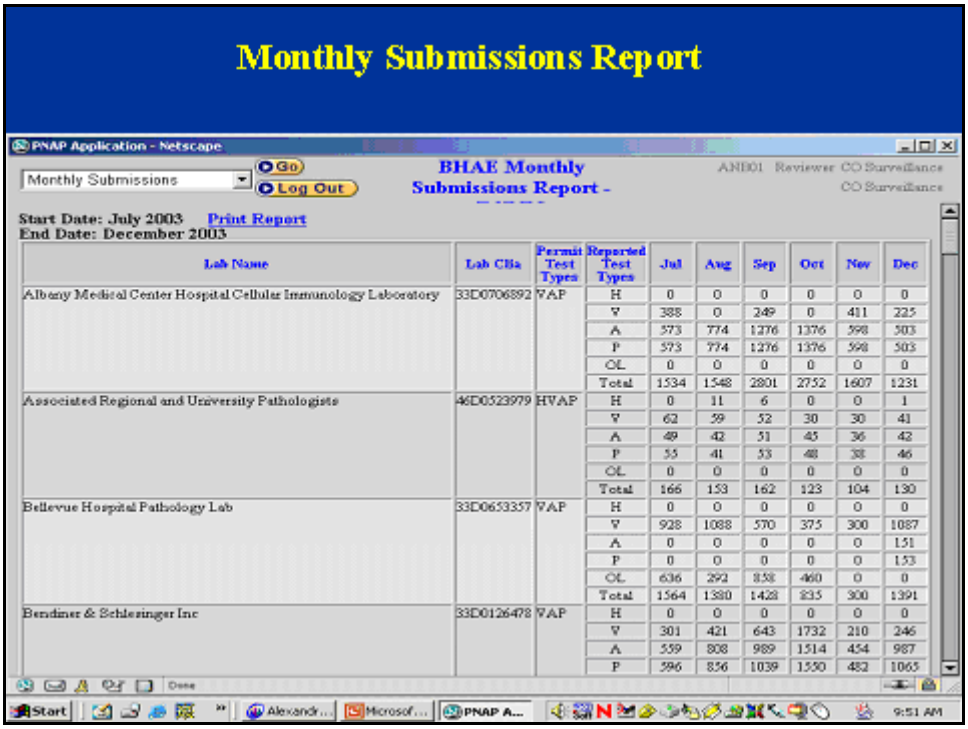
Method of submitting data (N=20 including nonelectronic methods)		
Virtual Private Network - HL7 (preferred)		0
Electronic file on diskette (acceptable)	Yes	7
U.S. Mail of paper records (acceptable)		13
Manual pick up of paper records (not preferred)		0
File protection (N=7)		
PGP Encrypted (preferred method)		2
Password protected (acceptable method)	Yes	4
No protection (poor method)		1
File formatting for electronic records (N=7)		
Excel (acceptable)	Yes	4
Tab or character-delimited (acceptable)		3
Space delimited (acceptable)		0

AIDS has been reportable since 1984. As of September 1, 1999, the Washington Administrative Codes (WAC 246-101) were expanded to require reporting, by name, of all cases of HIV infection. Laboratories are required to report—to their local or state health officer—AIDS-indicative CD4 counts (<200 cells per microliter or <14% of total lymphocytes), positive HIV viral load tests, confirmed HIV antibody tests, and other tests diagnostic of HIV infection.

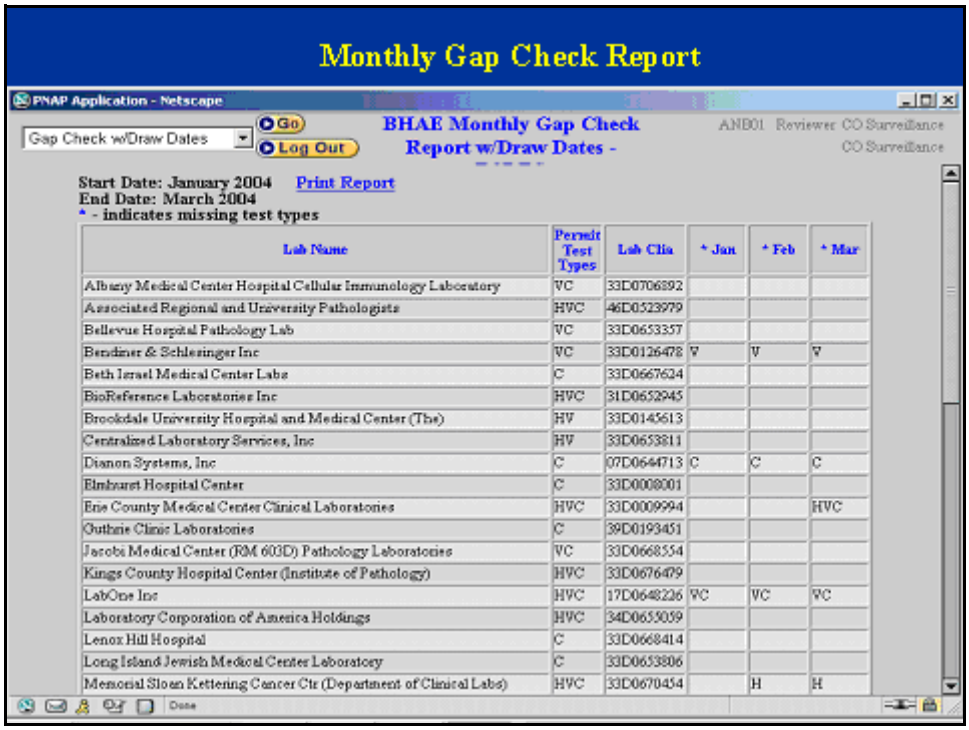
Appendix 5-B



Example: **Frequency Report** — Used to compare the licenses or permits held by each lab and their designated reporting schedule with the reports that are actually being submitted. This can be monitored by test type for any given month/year.



Example: **Monthly Submissions Report** — This report is used to monitor labs for any unusual change in volume of reporting by test type for each laboratory.



Monthly Gap Check Report

PNAP Application - Netscape

Gap Check w/Draw Dates | Go | Log Out

BHAE Monthly Gap Check Report w/Draw Dates -

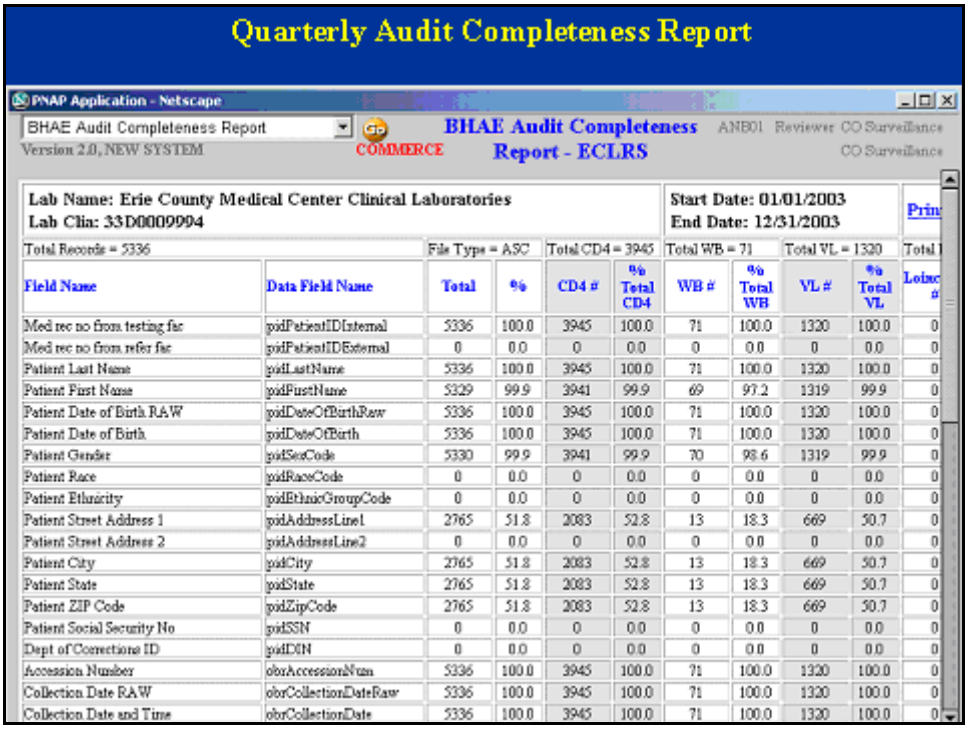
ANB01 Reviewer CO Surveillance
CO Surveillance

Start Date: January 2004 Print Report
End Date: March 2004
* - indicates missing test types

Lab Name	Permit Test Types	Lab Clia	* Jan	* Feb	* Mar
Albany Medical Center Hospital Cellular Immunology Laboratory	VC	33D0706892			
Associated Regional and University Pathologists	HVC	46D0523979			
Bellevue Hospital Pathology Lab	VC	33D0653357			
Bendiner & Schlesinger Inc	VC	33D0126478	V	V	V
Beth Israel Medical Center Labs	C	33D0667624			
BioReference Laboratories Inc	HVC	31D0652945			
Brookdale University Hospital and Medical Center (The)	HV	33D0145613			
Centralized Laboratory Services, Inc	HV	33D0653811			
Dianon Systems, Inc	C	07D0644713	C	C	C
Elmhurst Hospital Center	C	33D0008001			
Erie County Medical Center Clinical Laboratories	HVC	33D0009994			HVC
Guthrie Clinic Laboratories	C	39D0193451			
Jacobi Medical Center (RM 603D) Pathology Laboratories	VC	33D0668554			
Kings County Hospital Center (Institute of Pathology)	HVC	33D0676479			
LabOne Inc	HVC	17D0648226	VC	VC	VC
Laboratory Corporation of America Holdings	HVC	34D0655059			
Lenox Hill Hospital	C	33D0668414			
Long Island Jewish Medical Center Laboratory	C	33D0653806			
Memorial Sloan Kettering Cancer Ctr (Department of Clinical Labs)	HVC	33D0670454		H	H

Done

Example: **Monthly Gap Check Report** — This report is used to monitor gaps in reporting by specimen collection date. The Monthly Gap Check Report is shown above, but weekly and daily reports can also be generated. For each lab, for each month requested, a code in the column indicates that there was NO specimen collect date for that month. This report can identify a problem with the manner in which the lab has selected their data for submission.



Quarterly Audit Completeness Report

PNAP Application - Netscape

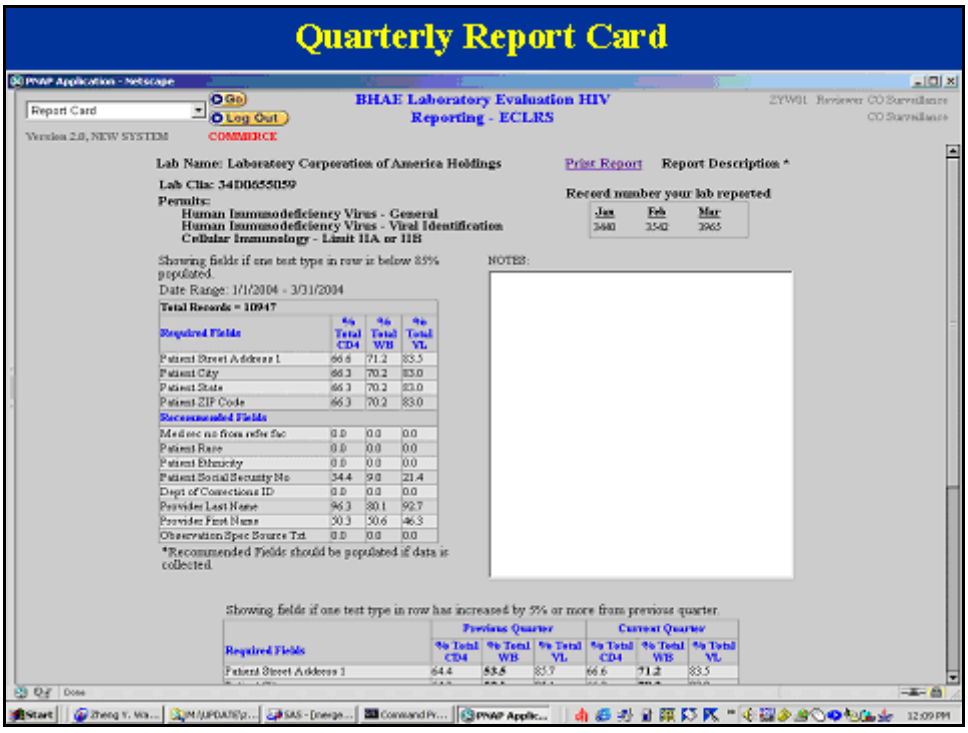
BHAE Audit Completeness Report - ECLRS

Lab Name: Erie County Medical Center Clinical Laboratories
Lab Clia: 33D0009994

Start Date: 01/01/2003
End Date: 12/31/2003

Total Records = 5336		File Type = ASC		Total CD4 = 3945		Total WB = 71		Total VL = 1320		Total
Field Name	Data Field Name	Total	%	CD4 #	% Total CD4	WB #	% Total WB	VL #	% Total VL	Loinc #
Med rec no from testing fac	pidPatientIDInternal	5336	100.0	3945	100.0	71	100.0	1320	100.0	0
Med rec no from refer fac	pidPatientIDExternal	0	0.0	0	0.0	0	0.0	0	0.0	0
Patient Last Name	pidLastName	5336	100.0	3945	100.0	71	100.0	1320	100.0	0
Patient First Name	pidFirstName	5329	99.9	3941	99.9	69	97.2	1319	99.9	0
Patient Date of Birth RAW	pidDateOfBirthRaw	5336	100.0	3945	100.0	71	100.0	1320	100.0	0
Patient Date of Birth	pidDateOfBirth	5336	100.0	3945	100.0	71	100.0	1320	100.0	0
Patient Gender	pidSexCode	5330	99.9	3941	99.9	70	98.6	1319	99.9	0
Patient Race	pidRaceCode	0	0.0	0	0.0	0	0.0	0	0.0	0
Patient Ethnicity	pidEthnicGroupCode	0	0.0	0	0.0	0	0.0	0	0.0	0
Patient Street Address 1	pidAddressLine1	2765	51.8	2083	52.8	13	18.3	669	50.7	0
Patient Street Address 2	pidAddressLine2	0	0.0	0	0.0	0	0.0	0	0.0	0
Patient City	pidCity	2765	51.8	2083	52.8	13	18.3	669	50.7	0
Patient State	pidState	2765	51.8	2083	52.8	13	18.3	669	50.7	0
Patient ZIP Code	pidZipCode	2765	51.8	2083	52.8	13	18.3	669	50.7	0
Patient Social Security No	pidSSN	0	0.0	0	0.0	0	0.0	0	0.0	0
Dept of Corrections ID	pidDIN	0	0.0	0	0.0	0	0.0	0	0.0	0
Accession Number	obrAccessionNum	5336	100.0	3945	100.0	71	100.0	1320	100.0	0
Collection Date RAW	obrCollectionDateRaw	5336	100.0	3945	100.0	71	100.0	1320	100.0	0
Collection Date and Time	obrCollectionDate	5336	100.0	3945	100.0	71	100.0	1320	100.0	0

Example: **Quarterly Audit Completeness Report** — This report displays the completeness rate for each of the required and recommended fields that get submitted. They are separated by type of test.



Quarterly Report Card

PNAP Application - Netscape

BHAE Laboratory Evaluation HIV Reporting - ECLRS

Lab Name: Laboratory Corporation of America Holdings
Lab Clia: 34D0655059
Permits:
Human Immunodeficiency Virus - General
Human Immunodeficiency Virus - Viral Identification
Cellular Immunology - Limit IIA or IIB

Print Report Report Description *

Record number your lab reported

Jan	Feb	Mar
3440	3542	3965

Showing fields if one test type in row is below 85% populated.
Date Range: 1/1/2004 - 3/31/2004
NOTES:

Total Records = 10947

Required Fields	% Total CD4	% Total WB	% Total VL
Patient Street Address 1	66.6	71.2	83.5
Patient City	66.3	70.2	83.0
Patient State	66.3	70.2	83.0
Patient ZIP Code	66.3	70.2	83.0
Recommended Fields			
Med rec no from refer fac	0.0	0.0	0.0
Patient Race	0.0	0.0	0.0
Patient Ethnicity	0.0	0.0	0.0
Patient Social Security No	34.4	9.0	21.4
Dept of Corrections ID	0.0	0.0	0.0
Provider Last Name	96.3	80.1	92.7
Provider First Name	30.3	50.6	46.3
Observation Spec Source Txt	0.0	0.0	0.0

*Recommended Fields should be populated if data is collected.

Showing fields if one test type in row has increased by 5% or more from previous quarter.

Required Fields	Previous Quarter % Total CD4	Previous Quarter % Total WB	Previous Quarter % Total VL	Current Quarter % Total CD4	Current Quarter % Total WB	Current Quarter % Total VL
Patient Street Address 1	64.4	53.6	83.7	66.6	71.2	83.5

Example: **Report Card** — A report card is sent to laboratories quarterly to help them monitor how well they are doing in their data submissions. Each lab can see where completion rates for required and recommended fields fall below 85%. A note field is

included and populated with comments tailored to each individual lab. These are usually based on the problems noted in the other reports, or problems seen with their data upon a manual review.

Example: **Report Card (cont)** — At the bottom of the report card, improvements in reporting are noted. Any field that was less than 85% complete on the previous audit appears here if there is a greater than 5 percent improvement in reporting this data element since the last report. It is helpful to give positive feedback to labs when their reporting improves.

Appendix 6

Changes in Laboratory Reporting Initiated by Electronic Laboratory Reporting (ELR)

LOINC (Logical Observation Identifiers Names and Codes)

PLEASE NOTE: The difference in the LOINC codes in this document and LOINC codes used in eHARS is temporary. The codes in eHARS will eventually be changed to match those used in this document.

Screening Tests

HIV-1 EIA

Test Name	Unit	Other	Specimen Source	LOINC
HIV 1 Antibody EIA	positive/negative	—	serum	29893-5 HIV1 Ab Ser Ql EIA
HIV 1 Antibody EIA	positive/negative	—	serum/donor	21007-0 HIV1 Ab Ser Donr Ql
HIV 1 Antibody EIA	positive/negative	—	unspecified	29327-4 HIV1 Ab Fld Ql

HIV-1/2 EIA

Test Name	Unit	Other	Specimen Source	LOINC
HIV 1&2 Antibody EIA	positive/negative	—	serum	31201-7 HIV1+2 Ab Ser Ql EIA
HIV 1&2 Antibody EIA	positive/negative	—	CSF	32602-5 HIV1+2 Ab CSF Ql

HIV-2 EIA

Test Name	Unit	Other	Specimen Source	LOINC
HIV 2 Antibody EIA	positive/negative	—	serum	30361-0 HIV2 Ab Ser Ql EIA

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

HIV-1 Rapid Test

Test Name	Unit	Other	Specimen Source	LOINC
OraQuick Rapid HIV-1/2 Antibody Test	positive/negative	only HIV-1 in oral fluid	oral fluid	35437-3 HIV1 Ab Sal QL EIA
OraQuick Rapid HIV-1 Antibody Test	positive/negative	—	blood	hold
Reveal Rapid HIV-1 Antibody Test	positive/negative	—	plasma/serum	hold
Uni-Gold Recombigen HIV	positive/negative	—	plasma/serum	hold
Uni-Gold Recombigen HIV	positive/negative	—	blood	hold
HIV-1 Rapid EIA	positive/negative	used only in delivery room	cord blood	33866-5 HIV1 Ab BldC Ql EIA

HIV-1/2 Rapid Test

Test Name	Unit	Other	Specimen Source	LOINC
Multispot HIV-1/HIV-2 Rapid Test	positive/negative	—	plasma/serum	hold
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	positive/negative	—	oral fluid	hold
OraQuick Rapid HIV-1/2 Antibody Test	positive/negative	—	plasma/serum	hold

Confirmatory Tests

HIV-1 IFA

Test Name	Unit	Other	Specimen Source	LOINC
HIV 1 IFA	positive/negative	—	serum	14092-1 HIV1 Ab Ser Ql IF

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

HIV-1 Western Blot

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 WB	positive/negative	—	serum	5221-7 HIV1 Ab Ser Ql IB
HIV-1 WB	positive/negative	band pattern	plasma/serum	not used by CDC
HIV-1 WB	bands appearing	band-specific LOINC	serum	not used by CDC
Cambridge Biotech HIV-1 Urine WB	positive/negative	—	urine	32571-2 HIV1 Ab Ur Ql IB
HIV-1 WB	positive/negative	—	CSF	16977-1 HIV1 Ag CSF Ql
HIV-1 WB	positive/negative	• OraSure HIV-1WB	oral fluid	35439-9 HIV1 Ab Sal Ql IB
HIV-1 WB	positive/negative	—	unspecified	34592-6 HIV1 Ab Fld Ql IB

*HIV-2 Western Blot **

Test Name	Unit	Other	Specimen Source	LOINC
HIV-2 WB	positive/negative	—	serum	5225-8 HIV2 Ab Ser Ql IB
HIV-2 WB	bands appearing	band pattern	serum	not used by CDC

**** All HIV-2 confirmatory testing should be conducted through CDC. Contact HICSB's Cases of Public Health Importance coordinator.***

Other HIV Detection Tests

HIV-1 P24 Antigen

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 P24 Antigen	positive/negative	EIA method	serum	18396-2 HIV1 p24 Ag Ser Ql EIA
HIV-1 P24 Antigen	positive/negative	unspecified method	serum	9821-0 HIV1 p24 Ag Ser Ql
HIV-1 P24 Antigen	positive/negative	neutralization confirm	serum	33660-2 HIV1 p24 Ag Ser Ql Nt
HIV-1 P24 Antigen	quantitative	unspecified method	CSF	16979-7 HIV1 p24 Ag CSF-aCnc

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

HIV Culture (HIV 1 or 2)

Test Name	Unit	Other	Specimen Source	LOINC
HIV Culture	positive/negative	—	blood	6429-5 HIV Bld Cult
HIV Culture	positive/negative	—	semen	6430-3 HIV Smn Cult
HIV Culture	positive/negative	—	unknown	6431-1 HIV XXX Cult

HIV-1 proviral DNA (qualitative detection of deoxynucleic acid)

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 Proviral DNA	detectable/non-detectable	probe and/or PCR	plasma/serum	30245-5 HIV1 DNA SerPl Ql PCR
HIV-1 Proviral DNA	detectable/non-detectable	probe and/or PCR	blood	9837-6 HIV1 DNA Bld Ql Amp Prb
HIV-1 Proviral DNA	detectable/non-detectable	probe and/or PCR	tissue	hold

HIV-2 proviral DNA (qualitative detection of deoxynucleic acid)

Test Name	Unit	Other	Specimen Source	LOINC
HIV-2 Proviral	detectable/non-detectable	probe and/or PCR	plasma/serum	34699-9 HIV2 SerPl Ql PCR
HIV-2 Proviral	detectable/non-detectable	probe and/or PCR	blood	25841-8 HIV2 DNA Bld Ql PCR
HIV-2 Proviral	detectable/non-detectable	probe and/or PCR	unknown	25842-6 HIV2 DNA XXX Ql PCR

**** All HIV-2 detection testing should be conducted through CDC. Contact HICSB's Cases of Public Health Importance coordinator.***

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

HIV-1 RNA (qualitative detection of ribonucleic acid)

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 RNA	detectable/non-detectable	probe and/or PCR	plasma/serum	25835-0 HIV1 RNA SerPl Ql PCR
HIV-1 RNA	detectable/non-detectable	probe and/or PCR	blood	5017-9 HIV1 RNA Bld Ql PCR
HIV-1 RNA	detectable/non-detectable	probe and/or PCR	unknown	5018-7 HIV1 RNA XXX Ql PCR

HIV-2 RNA (qualitative detection of ribonucleic acid)

Test Name	Unit	Other	Specimen Source	LOINC
HIV-2 RNA	detectable/non-detectable	probe and/or PCR		hold

HIV-1 DNA/RNA (qualitative detection of deoxyribonucleic acid a/o ribonucleic acid)

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 DNA/RNA	detectable/non-detectable		plasma/serum	hold

CD4+ T-Lymphocyte Tests

CD4 Count

Test Name	Unit	Other	Specimen Source	LOINC
CD4 T-lymphocyte count	cells/µl	—	blood	8127-3 CD4 Cells # Bld
CD4 T-lymphocyte count	cells/µl	—	unspecified	20605-2 CD4 Cells # XXX

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

CD4 Percent

Test Name	Unit	Other	Specimen Source	LOINC
CD4 T-lymphocyte percent	%	—	blood	8128-1 CD4 Cells % Bld
CD4 T-lymphocyte percent	%	—	unspecified	20606-0 CD4 Cells % XXX

Viral Load Tests

HIV-1 RNA Viral load - grouped by minimum detection limit, various methods

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 viral load, min det ≤400 c/ml	copies/ml	• Amplicor Monitor (**standard**): 400-750,000	plasma/serum	41513-3 HIV1 RNA #SerPl Amp Prb DL 400 copies
HIV-1 viral load, min det ≤2.6 logc/ml	log copies/ml	• Amplicor Monitor (**standard**): 2.6-5.9	plasma/serum	41514-1 HIV1RNA SerPl Amp Prb DL 2.6 log copies-log count
HIV-1 viral load, min det ≤75 c/ml	copies/ml	• Amplicor Monitor (**ultrasensitive**): 50-75,000 • NucliSens QT: 40-15,000,000 • Versant bDNA: 75-500,000	plasma/serum	41515-8 HIV1 RNA #SerPl Amp Prb DL 75 copies
HIV-1 viral load, min det ≤1.9 logc/ml	log copies/ml	• Amplicor Monitor (**ultrasensitive**): 1.7-4.7 • NucliSens QT: 1.6- 7.2 • Versant bDNA: 1.9-5.7	plasma/serum	41516-6 HIV1 RNA SerPl Amp Prb DL 1.9log copies-log count

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

HIV-1 Viral load - unspecified or unknown method & unknown minimum detection limit

Test Name	Unit	Other	Specimen Source	LOINC
HIV-1 RNA	copies/ml	any method	serum/plasma	20447-9 HIV1 Viral Load SerPl PCR
HIV-1 RNA	log copies/ml	any method	serum/plasma	29541-0 HIV1 Log Viral Load Plas PCR

HIV-2 Viral load - unspecified or unknown type

Test Name	Unit	Other	Specimen Source	LOINC
HIV-2 RNA	copies/ml	—	serum/plasma	hold
HIV-2 RNA	log copies/ml	—	serum/plasma	hold

Viral Susceptibility Tests

HIV-1 Genotype (viral resistance/susceptibility)

Test Name	Unit	Other/misc	Specimen Source	LOINC
HIV-1	Protease and RT nucleotide sequence; mutations associated with HIV drug resistance det/nondetectable	ELR to states should consist of a text file (“FASTA”) representing the nucleotide sequence	plasma/serum	hold
HIV-1			blood	hold
HIV-1			dried bloodspot	hold
HIV-1			dried plasma/serum spot	hold

HIV-1 Phenotype (measured viral drug resistance/susceptibility)

Test Name	Unit	Other/misc	Specimen Source	LOINC
HIV-1	IC50	antiretroviral agents	plasma/serum	hold
HIV-1	IC50	antiretroviral agents	dried plasma spot	hold

WARNING: The LOINC short name (i.e., name listed under the LOINC number) may change. It has been included because some laboratories find the short name useful. The LOINC number, however, will not change.

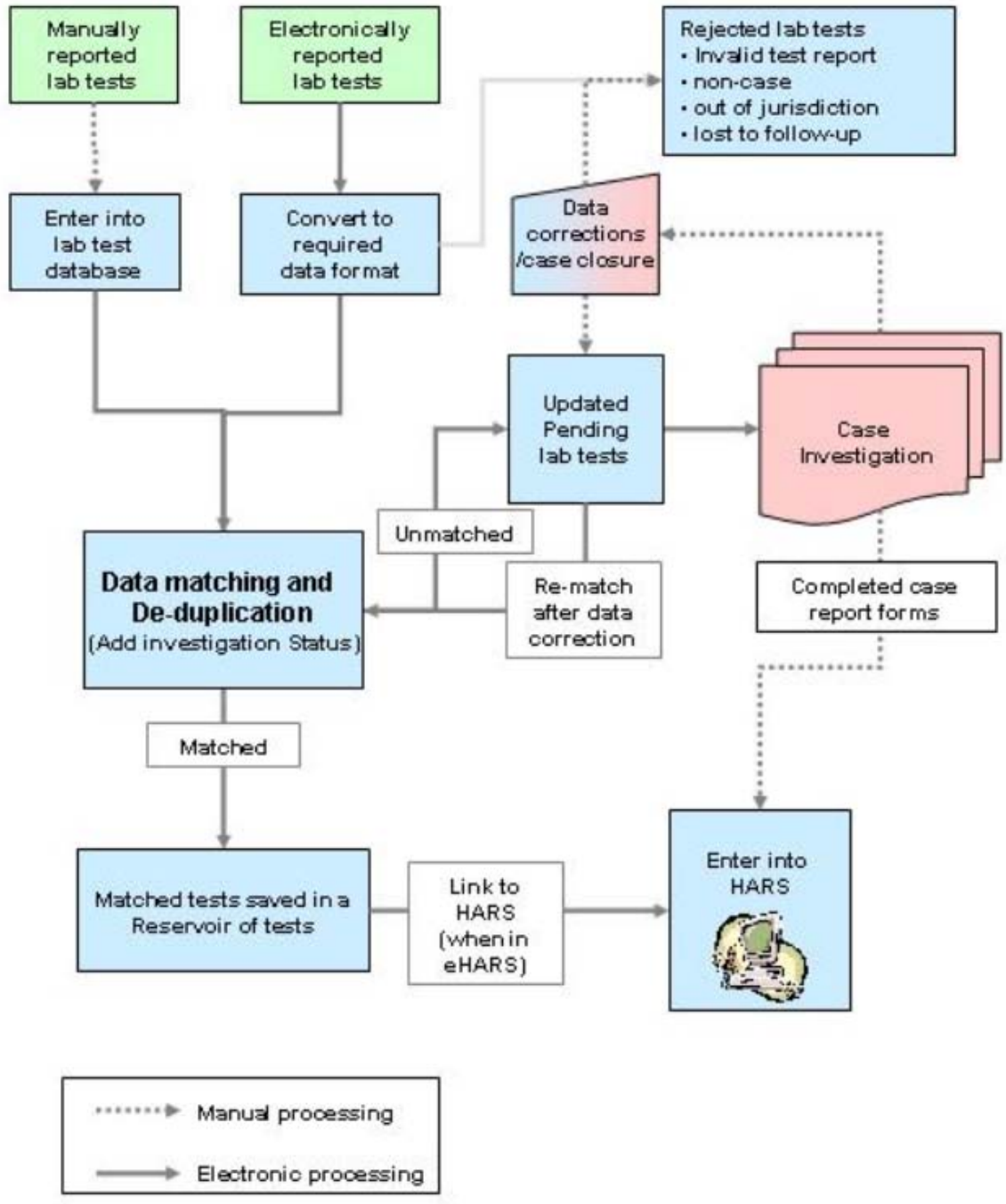
Appendix 7

Case Follow-up from a Lab Report

Appendices 7-A - 7-C

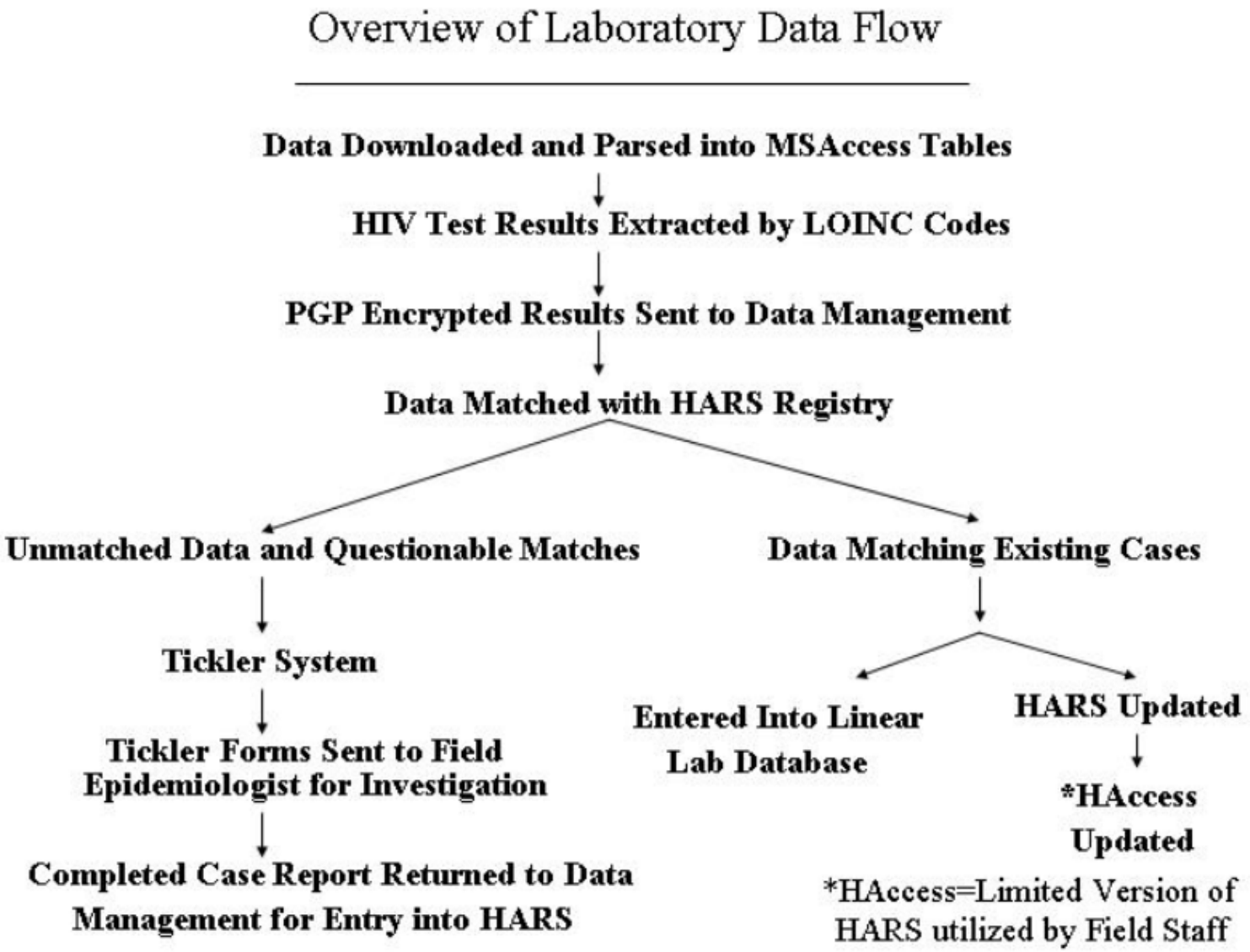
Appendix 7-A

Processing Laboratory Test Reports



Appendix 7-B

Overview of Laboratory Data Flow



Appendix 7-C

HIV/AIDS Surveillance System Overview